UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

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Monday, May 13, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped Deposition of JAMES E. RAFALSKI, held at Weitz & Luxenburg PC, 3011 West Grand Avenue, Suite 2150, Detroit, Michigan, commencing at 9:20 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

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DEPOSITION EXHIBITS
JAMES E. RAFALSKI
May 13, 2019

DEPOSITION EXHIBITS

PROCEEDINGS

(May 13, 2019 at 9:20 a.m.)

(The following proceedings were conducted off the videotaped record.)

MR. NICHOLAS: Before we get started, Mr. Fuller, counsel for plaintiffs, just handed me a Touhy authorization letter that's dated April 12th of 2019. This is the first we've seen it. I'm going to proceed with the deposition.

I will reserve our right to come back if there's anything about our receipt of this or something in the letter that requires us to come back and ask more questions since we're seeing it for the first time, and that's what I wanted to say.

MR. FULLER: Sure. And we'll put on the record that as everyone here knows, Mr. Rafalski is a former DEA agent, therefore Touhy authorization would have to be obtained, similarly to the 20 former DEA employees that the defendants

requested Touhy clearance on before disclosing some of their expert reports.

I've been asked to remind that the DEA wasn't noticed of this depo, even though he's a former agent, by the defense. They weren't necessarily happy with that. They asked for everybody to comply with the Touhy authorization, which, similar to the other authorizations in this case, allows the witness to testify to -- well, a little different with Rafalski because he's reviewed a lot of the documents produced by all the defendants, testified from the discovery produced in this case and anything nonprivileged as set out in the Touhy authorization.

MR. NICHOLAS: Okay. There's too many things to argue about in this case to get into a big argument --

MR. FULLER: Sure, sure.

MR. NICHOLAS: -- but I will just say that he's your retained

expert. You've had this letter for a month; you're just giving it to us today.

So I don't get the part where the DEA -- if the DEA is unhappy, maybe they're unhappy with you guys, but they shouldn't be unhappy with us because he's your person.

But like I said, we don't need to spend any more time on it.

THE VIDEOGRAPHER: Ready to begin?

MR. NICHOLAS: I am.

(Whereupon the videotaped record begins.)

THE VIDEOGRAPHER: We're now on the record. My name is David Lane, videographer for Golkow Litigation Services. Today's date is May 13th, 2019. Our time is 9:22 a.m.

This deposition is taking place in Detroit, Michigan in the matter of National Prescription Opiate Litigation. Our deponent today is James E. Rafalski.

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Counsel will be noted on the stenographic record. Our court reporter is Mike Miller, and he will now swear in the witness.

JAMES E. RAFALSKI, having been duly sworn, testified as follows:

EXAMINATION

BY MR. NICHOLAS:

Q. Good morning, Mr. Rafalski. My name is Bob Nicholas. I represent AmerisourceBergen. I'm here to ask you questions in connection with the MDL opioid litigation and specifically the Track 1 and Track 2 -- just the Track 1 cases that are currently scheduled to go to trial in October.

A. Good morning, sir.

Q. Good morning.

You are here as a retained expert on behalf of the Track 1 plaintiffs in this case; is that right?

A. Yes, sir, I am.

Q. Okay. And you are being paid for your time?

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A. Yes, sir, I am.

Q. Tell me what you're being paid in terms of just what's your rate?

A. $300 an hour.

Q. Okay. And is that for everything you do or is that for -- just for reviewing papers and in connection with your report?

A. It's for everything I do.

Q. So are you -- you're not being paid a different rate to testify?

A. Yes, sir.

Q. You are being paid a different rate to testify?

A. Yes, for my deposition, or for this deposition today, it's at $500 an hour.

Q. Okay. And if there's a trial and you testify at the trial, that would be at $500 an hour?

A. That's never been discussed, so I don't know what rate that would be.

Q. Okay. Might be higher?

A. I would guess it at least will be $500 an hour.

Q. Sure. Tell me, if you could --

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A. Could I make a little correction to that?

Q. Sure, of course.

A. So when I first started, it was at a $200 rate. And then at some point I was approached and it increased to 300. So my initial rate was at $200 an hour.

Q. When did you start?

A. August of 2017, I signed my retainer.

Q. Okay. And so your August 2017 retainer had a rate of $200 an hour?

A. Yes, sir.

Q. And how long was that your rate?

A. Until -- I believe it was October of 2018.

Q. Okay.

A. Either August or October of 2018.

Q. And you said you were approached. What do you mean -- who approached you?

A. Well, in discussions with one of the attorneys, my original retainer

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expired and we had some conversations about my rate. It came to my attention that other experts of at least equal skill were receiving $300 an hour, so when I brought that topic up, there was an agreement to pay me $300 an hour.

Q. Okay. So it was in the form of a negotiation; is that right?

A. Well, I guess you could consider that. It was more of a conversation, came up in conversation so there was no need to negotiate. It was just agreed upon when it was brought up.

Q. Okay. I'm going to get back to the work you've done in a second, but let me just ask you just a couple of basic questions about yourself.

You were a police officer for a number of years, right?

A. Yes, sir.

Q. Okay. How many years?

A. 27 total with two different police departments, police agencies.

Q. Okay. Which were the police agencies?

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A. The first one was the Wayne County Sheriff's Department, 1976 to 1981, and I left employment at the Wayne County Sheriff's Department, which would be in Detroit, Michigan, all of Wayne County, that's where we're at today. And then I moved to Romulus Police Department, which is Romulus, Michigan. That's the community where probably most everyone flew in. It's around the Detroit Metropolitan Airport.

Q. Okay. So 27 years as a police officer, right?

A. Yes, sir.

Q. Okay. And then you joined the DEA; is that correct?

A. At some point. I retired in 2002. I did not join the DEA until 2004.

Q. What happened in those two years? Just retirement?

A. No, I kind of had an aspiration to be a teacher, so I started to do some teaching. I got a vocational certification, and I was a teacher with -- I did some substitute teaching and some baseball coaching with the Romulus school district,

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and then I did vocational certification with the Livonia Public Schools and I taught there for one year before leaving for the DEA.

Q. What did you teach?

A. I was called a shared time teacher. So in Michigan, property owners pay property taxes which fund the public schools, while private schools are tuition based. So there was some kind of decision, and I don't know the law or the legality of it, but -- I shouldn't say legality, but what caused it.

So then public school teachers would go into private schools and instruct private students, mostly religious schools, faith-based schools. So I taught computers, some mathematics and some physical education.

Q. Okay. And after a couple of years of that, you joined the DEA; is that correct?

A. Yes, sir.

Q. And you were with the DEA from when to when?

A. 2014 until June 2017.

Q. 2014 or 2004?

A. 2004.

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Q. Okay.

A. Sorry.

Q. It's okay. 2004 to 2017.

Now, during the time that you were at the DEA, what was your position?

A. Diversion investigator.

Q. Okay. Did that job ever change?

A. My title, no, sir.

Q. Your title, yeah.

A. No, sir.

Q. Okay. And in 2017, did you retire, full-time retire or what?

A. Yes, sir, that was my intention.

Q. Okay. But then you got this thing?

A. Yes, sir.

Q. Okay. Now, just so I know a few more things, you are not -- let me start again.

Have you ever been certified as an expert witness in a case before?

A. I have not been certified before, no, sir.

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Q. Have you ever served as an expert witness on a consulting basis before?

A. No, sir, I have never served as an expert in the capacity of a consultant.

Q. Okay. Have you ever written any articles that were published?

A. No, sir.

Q. Have you ever written anything of any kind that was published?

A. As a police officer, I wrote an article at the request of the Detroit News. It was in regards to the effectiveness of the DARE program.

Q. Okay. So you wrote something for the Detroit -- is it the Detroit News?

A. Detroit News, it's the publication.

Q. Did that used to be the Detroit Free Press or is that a different paper?

A. Different paper. Still two papers in Detroit.

Q. Okay. Was that like an op-ed, like an editorial kind of thing?

A. Sure. They published two, I guess, opinions, a pro and a con opinion.

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Mine was the pro opinion of DARE, and there was a side-by-side con opinion of the effectiveness of that program.

Q. Okay. So you wrote that. Is there anything else you've ever written that's been published?

A. Not that I'm aware of, not that I gave any authorization for, no, sir.

Q. Okay. Have you -- and this is pretty obvious, but you're not an attorney; is that correct?

A. Not an attorney, no, sir.

Q. So in giving your opinions today, you're not trying to give legal opinions; is that right?

A. Well, the opinion I'm trying to give is based on my training and experience and my knowledge of the law and the regulations that are required to be adhered to by the companies. I'm not publishing a legal opinion as an attorney.

Q. Well, what I'm asking you is whether you -- are you offering today or in your report a legal -- a legal conclusion?

A. I think, yes, I am.

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Q. Okay. Let me ask you a little about the work you've done in connection with this report.

First of all, the report is 180 pages, I believe.

A. It is, sir.

Q. Did you write it?

A. Yes, sir.

Q. Okay. You wrote it yourself or did you write it with help?

A. I wrote it with help.

Q. Okay. How much time did you spend preparing your report?

A. Well, I didn't keep track if you're going to ask me the exact hours, but I would say a considerable amount of time. It pretty much consumed me.

Q. When did you start working on the report?

A. Well, probably in the fall of 2018, I started having discussions about the type of documents and records that I would need, some of the topics in potential depositions, questions I would need to answer. So I started to give the framework

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and the guidelines of what information would be required. It was around that time when I had a pretty clear understanding of what I would give an opinion on.

When I first started I was more of a consultant than an expert witness, so, you know, I wasn't exactly sure what I was going to be asked to give an expert opinion on.

Q. So until the fall of 2018, is it correct that you were working as a consultant for the plaintiffs in this case?

A. Well --

Q. Starting in 2017.

A. -- I guess that would be my capacity. I didn't do any testifying, so I guess I wouldn't be considered an expert witness. I don't know that there was a capacity at that time, so I think that's a fair statement.

Q. But did you work -- did you put work into this case from the time you were retained in 2017 up until 2018 when you started working on the report?

A. I would say yes, but it would

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be a different kind of work because obviously when the discovery came in and the records were available and the depositions began, then there was a different kind of information. But there was always a little bit of a process because I knew at some point I was going to be potentially asked to publish an opinion.

Q. Okay. Do you know how many hours you spent or how many days or how many weeks you spent working on the case from two-thousand-and -- let's say from the time you were retained in 2017 until the fall of 2018?

A. Somewhere a little below or above 400 hours.

Q. Okay. And that takes you up to the fall of 2018, right?

A. That takes me today.

Q. I see. So you spent about 400 hours from the beginning of being retained until today working on this matter?

A. Yes, sir.

Q. Okay.

A. I'd like to add that I'm

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probably not as diligent on my billing as I should be. I know some people might bill for every minute. I don't do that, so -- but that would be an accurate amount of time that I -- at least that I submitted for billing.

Q. Okay.

A. I probably spent more than 400 hours on the project.

Q. So do you know how much in terms of dollars you have submitted for billing?

A. Well, 101,000 and a little over that.

Q. Okay. Tell me how you made -- tell me how you obtained the materials you needed to prepare your report?

A. Both in -- mostly in verbal requests and discussions. I think there were some -- I crafted some e-mails, which had specific types of documents that I would need and submitted them to the attorneys. That started a discussion on the types of documents I'd need to review.

Q. Okay. And how did -- if you don't mind my asking, how did you know what

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to ask for? There are millions of documents in this case and many, many depositions. How did you know what to request?

A. Based on my experience in conducting similar type of investigations of both distributors and manufacturers, I had a pretty good idea of the type of records and documents or questions I would need answered to formulate an opinion.

Certainly there were things that -- documents that were submitted or deposition answers or questions that I hadn't thought of, but they also became available to me.

Q. How did they become available to you?

A. Well, in drafting my report, there would be certain topics regarding the maintenance of effective controls, suspicious order systems. People would also assist me in reviewing the documents and they would find articles or statements or policies that would be brought forward to my attention, sometimes with a written explanation or draft explanation, and I'd review those and

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either -- not dismiss them, but review them and either incorporate them or not incorporate them in my report.

Q. When you say people would review things and send them to you, are you talking about the plaintiffs' attorneys?

A. Yes, sir.

Q. Okay.

A. Only the -- well, let me correct that.

My communications would flow through just a couple of specific attorneys, and they would come back from them. So I don't know if they were attorneys or legal aides or -- I don't know exactly who would draft some of the information I would review.

Q. What were the name -- who were you dealing with?

A. Mr. Fuller, Mr. Elkins, and for a period of time a Laura Baughman. I think she left her law firm. So those were primarily the three people.

Q. Okay. Did you have anyone else assisting you with this report?

A. No, sir.

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Q. Who typed the report?

A. I typed it.

Q. Now, you said that they would -- that Mr. Fuller and Ms. Baughman and Mister -- I'm sorry --

A. Elkins.

Q. -- Elkins, who I guess is sitting next to Mr. Fuller?

A. He is.

MR. NICHOLAS: Hello, Mr. Elkins.

MR: ELKINS: Good morning.

BY MR. NICHOLAS:

Q. Would send you drafts of things and you would review them. What do you mean? Did they send you drafts of portions of the report?

A. Sure. There may be a section of the report, maybe a policy, or there may be some specific documents that they would give an evaluation of or at least describe it, and I would review it and make edits, corrections, deletions and either incorporate it into my report or not incorporate it in my report.

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Q. And is it fair to say that that's how the report was written, that the plaintiffs' lawyers sent you draft sections, you would review them and revise them as you saw fit, and that is how the report came to be?

A. I wouldn't say that's an accurate statement. I mean, I wrote the report, it's my report. I put pen to paper. There may be sections in here that I incorporated, but every section would have been edited, drafted, corrected or reviewed by me.

Q. Right.

A. So there's no sections in here that I just plugged in that someone else wrote. It's all my work product.

Q. Which -- roughly, okay? Can you tell me how -- what percentage of this report started with a first draft from the plaintiffs versus a first draft from you?

A. I'm not really sure how to answer that. Are you looking for like a percent or --

Q. I don't know. Number of pages.

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You know, how much of this 180-page report, how many pages -- for how many pages did you write the first draft and how many pages did the plaintiffs write the first draft?

A. Well, I'm unsure of how to give you a number, because I really didn't -- it wasn't a kind of draft where I knew exactly how many pages the first time. It was substantial at the beginning, I would say around the 100-page mark, and then as more records were found, more documents, as the report was written, one section would trigger an analysis that would lead to another section and it would probably be a lot thicker if I would have had the ability to work around the clock and stay up all night because it's -- you know, it's a complex matter.

There's numerous companies, millions and millions of documents. I by no means am trying to represent to you or the court that I've read every document in regards to the discovery because I don't think that's physically possible.

Q. Do you know whether you --

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well, so you have not reviewed all the documents that have been produced in discovery, right?

A. No, that would be impossible.

Q. Right. Do you know whether you've reviewed the most important documents in the case?

A. I believe I have with the assistance I was provided, being I gave the guidelines of the type of documents I wanted to be provided or reviewed. And I'm -- I'm fairly confident -- I'm very confident that I've got enough information to make this opinion, and I'm sure that if I've missed some documents, I'm going to hear about it in the next two days.

Q. Who -- who made -- who sent you the documents? The plaintiffs' lawyers?

A. Yes.

Q. Okay.

A. Primarily Mr. Elkins.

Q. Okay. So, for example, if there were -- I don't know how many depositions have been taken in the case, but there have been many, many depositions.

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How did you know -- how did you know which ones to ask for, which transcripts to ask for?

A. Well, at the beginning I started to read them, and I realized that it was impossible for me to read and take notes, so I read a couple at the beginning which, by probably more luck than anything because they just started to come to me in writing, not electronic, I read some depositions that were key to the discovery -- I mean key to the investigation.

At a later point, attorneys obviously would know based on the type of questions I wanted answered and the positions of the people who were being deposed that some depositions were more crucial than others.

Q. So the attorneys made the decisions as to which of the depositions you should review, right?

A. I don't know if they made the decisions. I think they pointed me to depositions where they thought there was content that would be important to me, and I

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would review those sections of those depositions.
Q. Okay. So just by way of example, do you know who Kyle Wright is?
A. I am -- I do. Yes, sir.
Q. Okay. Did you read his deposition?
A. I believe I read a portion of it. I didn't read the entire deposition.
Q. Because I don't think your report reflects that you've reviewed his deposition. That's why I'm asking.
A. I'm not sure that he had any information in his deposition I would have used, but I did review -- I didn't review his entire deposition, but I do recall that I did review some of it, yes, sir.
Q. If you reviewed his deposition, is there a particular reason why you didn't say in your report that you reviewed his deposition? Was it just an oversight?
A. I don't know that I would be required to put that in my expert report, whether or not -- I reviewed a lot of depositions and not all of them are --

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there's no notation that that occurred in this report.
Q. Well, I think we need to know everything you reviewed in order to be able to ask you questions about your report, so if there are -- are you saying there are things that you reviewed in connection with this report that you didn't identify as having reviewed? Kyle Wright's deposition is one example. Are there others?
A. Well, recently I reviewed a portion of Thomas Prevoznik's deposition. I'm sure there are some other depositions that I reviewed that aren't cited in my report. Possibly those individuals didn't have any information that would have provided me with any guidance in my opinion.
For example, I recall reading one on a sales personnel. Might have been from AmerisourceBergen or Cardinal, and really, there was nothing relative to that that would help me make my expert opinion in regards to the conduct of that company.
Q. So you didn't identify that in your report as something you read?

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A. No, sir. I did prepare a list of documents that I utilized and provided it to the attorneys at their request.
Q. Okay. So there are documents that you reviewed for this report, and right now we don't know what they are because you haven't identified them. That's all I want to know.
A. That's a true statement. There were probably some depositions that I took or some records -- not every record I looked at is documented in this report. There's multiple, multiple depositions. There's 5 million documents. I was never instructed as a witness that I had to keep a laundry list of everything I looked at or everything I reviewed.
Q. Did you find anything in your --
MR. FULLER: Form to the last question.
MR. NICHOLAS: Say again.
MR. FULLER: Form to the last question. Counsel, you stated that --
MR. NICHOLAS: It's okay. You

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made your objection.
MR. FULLER: No. You stated that there are documents in here that he reviewed related to his report. I think the testimony is that he reviewed documents but they didn't impact his report.
MR. NICHOLAS: They didn't impact your report.
BY MR. NICHOLAS:
Q. In your review of all of these documents and all these depositions that you read, did you find anything in any of them that was in any way favorable to any of the defendants in the case?
A. There were a couple of things that I thought were -- I wouldn't say favorable. That I thought were a positive measure by the companies.
Q. Did you reference those in your report?
A. Both of the things that I'm thinking of happened right at -- the timeline would have been right near the end of the 2013 -- or, I mean, sorry, one was right

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before 2017, and the other one was with a company and right about when they were making those changes, they gave up their authority or their distribution of controlled substances, so I did not make comment on that. It didn't impact their conduct during the timeline of my report.

Q. That's one. What was the other one?

A. Well, there's two. One was right near the end of -- in 2017, they were making some changes to their suspicious order monitoring system that I thought were pretty positive and significant, but it was right at the very end of the timeline. That was one company. That would have been McKesson.

And then CVS made some changes right near the end of the time they handled controlled substances. I think it was around 2000 -- I don't want to say a date. I want to check my report. I don't want to be inaccurate. But at some point they just gave up distributing controlled substances, and it was right near that time period.

Q. Are these two facts in your --

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A. No, sir.

Q. You didn't put those in your report?

A. No, sir.

Q. Other than those two things, is there anything that you reviewed in all of the documents that was in any way positive or favorable to any of these 12 defendants?

A. I would have to say, sir, in looking at all the records, in the records that I asked for -- and I'm going to restate, I didn't read all 5 or 6 million documents that were provided. The documents that I reviewed or that were provided to me, I would have to say no.

There was -- I was actually somewhat shocked by the level of failure in the documents that I reviewed, by the companies.

Q. The documents that were sent to you by the plaintiffs' lawyers?

A. And that I elected to review based on what they were, policies, procedures, descriptions of systems, particular depositions where people that had

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knowledge how the system would work or whether it was utilized.

So it wasn't just -- just so I'm clear, I wasn't being spoon-fed just particular documents. I just want to make it clear to the court and to the judge that I couldn't physically look at every document.

Q. How many documents did you review, do you know?

A. Well, no, I have no idea. Extensive.

Q. Okay. Did you speak with plaintiffs' lawyers in connection with drafting this report?

A. Could you explain that question?

Q. Did you talk to Mr. Fuller or Mr. Elkins or Ms. Baughman about the content of the report?

A. I think there was some general conversation, just -- just not what to write, but I've never written an expert opinion, report before, so obviously I needed a little bit of guidance on how it would flow. So how it's laid out, the beginning with my

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experience, somehow how it's divided by company. I mean, some of the general formatting, you know, that I had to come to some conclusions.

I was told what topics that I would be expected to give an opinion on. I was also told to stay within the guidelines of those opinions, not to, you know, get into topics that were outside of that, those -- my opinions.

Q. And what topics were you told to give an opinion on?

A. Maintenance of effective controls to prevent diversion, which is both in the law and federal regulations, and suspicious -- designing and operating a suspicious order system, CFR 1301.74(b).

Q. Did you ever meet with any of the other experts in the case?

A. I have.

Q. That are -- let me start again.

Did you ever meet with any of the other experts in the case who were working with the plaintiffs?

A. Yes, sir.

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Q. Okay. Who did you meet with?
A. Physically I had a meeting with Mr. McCann in Arlington on two different occasions.
Q. Okay.
A. By telephone, there was an expert witness, and I hopefully have his name correct. I think it was Seth Whitehill or Whitehall.
Q. Uh-huh.
A. And then there was another expert opinion and -- I was anticipating this question, I was trying to remember. I believe -- I only remember her first name. I think it was Hui, but I don't -- I'm sorry -- I don't -- you know, I have a recollection --
Q. That was a phone call or a meeting?
A. That was a phone conversation. One phone conversation with her. I had two phone conversations with Mister -- Seth. I remember his first name. It was either Whitehill or Whitehall.
Q. And two in-person meetings with Mr. McCann? One?

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A. Well, I don't know so much that I would call them meetings.
Q. What would you call them?
A. Well, the first one is we went to his company in -- me and some other people, and that's when they had received the ARCOS data, and it came in in a native format, just as a string of numbers, EDI format. I think they were maybe anticipating it was going to come in in a different, more readable style.
So I met with them just to kind of give them some guidance on what the ARCOS materials should look like. Would you like an example?
Q. Not right now. Let me ask you --
A. And then the second meeting?
Q. Yeah.
A. The second meeting was right after Christmas. There was some kind of a work product that Mr. McCann did, and it went out to some groups of people, and I was asked to go to his office and sit in the conversation room in case I received any

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calls from plaintiff attorneys that had questions about the data that they had received. And I received no calls, so it was just -- sat in a room, had a casual conversation with Mr. McCann, but it wasn't in regards to any of the analysis or any of the work.
Q. Okay. I need to -- I think I need to understand this just a little better.
A. Sure.
Q. So the first meeting with Mr. McCann had to do with the ARCOS data and making it sort of more understandable?
A. Yes.
Q. Right?
A. So -- yep.
Q. Okay.
A. So you want an explanation of it?
Q. No.
A. Okay.
Q. I guess what I want to know is: Was anyone else there?
A. Yes.
Q. Who else was there?

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A. There was a couple other experts -- well, I guess consultants, former DEA employees were there present, and also there was one attorney, one plaintiffs' attorney.
Q. Who were the other consultants?
A. James Geldhof. I'm trying to think who was all there. Frank Younkers, and I think there may have been one more. I'm not sure. And one attorney.
Q. Who was the attorney?
A. Peter Mougey.
Q. How long was that meeting?
A. Well, I wouldn't really consider it a meeting. It was kind of a --
Q. Were you in a room together?
A. Yes.
Q. Okay.
A. So it wasn't like a formal meeting where we had discussions. There was just basically some back-and-forth on trying to understand how to get the ARCOS into a usable format.
Q. Whether you call it a meeting or all sitting in a room together and

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talking, how long was it?
A. Oh. It was the better part of a day. The first day, six or seven hours. The second day it was a partial part of the day.
Q. Okay. So it was a meeting that occurred over two days?
A. Yeah.
Q. And that was in Arlington, Virginia?
A. Yes, sir.
Q. All right. Had you ever met any of those guys before?
A. I had. Well, I had not met Mr. McCann before.
Q. Okay.
A. But I had met Mr. Frank Younkers and James Geldhof. There was another expert, and his -- I remember his name. David Schiller. I had never met him prior to that day. He was a former DEA employee also.
Q. And Younkers and Geldhof you knew from what, DEA days?
A. Yes.

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Q. Okay. I don't want to get into a big thing about it, but where did they -- how did you know -- how did you know them from DEA days? What did they do?
A. Mr. Geldhof, he was the diversion program manager.
Q. Where?
A. Let me back up.
Q. Yeah.
A. When I first started, he was my immediate supervisor for a short period of time, and then he was promoted, so he was in the Detroit division office as the diversion program manager, which would be one level above my supervisor.
Frank Younkers was the group supervisor in the Cincinnati DEA office, Cincinnati, Ohio. I did some cases in Cincinnati and I met him just as an introduction and say hi. I never really worked with him or had any supervision by him.
Q. Okay. But Mr. McCann and Mr. Whitehall and the woman that you referenced are all people you'd never met

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before?
A. That's correct.
Q. You were introduced by the plaintiffs' attorneys basically?
A. Yes, sir.
Q. Okay. And the phone call with Mr. Whitehall was about what?
A. Well, my expert opinion has to deal with the companies' actions and compliance with regulations and the law, and my -- I guess my understanding of what Mr. Whitehill does is he looks at the companies for more of a larger corporate type of compliance, maybe how the companies set up their compliance in more of a big, broader overview.
I really didn't see any connection between what his opinion was going to be and my opinion, but at the request of plaintiff counsels, we had a couple of discussions.
Q. So you talked more than once?
A. Yes, sir.
Q. On the phone?
A. Yes, sir.

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Q. Were lawyers on the phone with you when you talked?
A. Yes, sir.
Q. Who were they?
A. Well, for sure I knew Amy Quezon was on the phone. She's the one who arranged the phone conferences. I believe Mr. Fuller might have been. I'm not sure. I think he might have been off and on. And it's possible Mr. Elkins. It wasn't the kind of a formal meeting where everyone announced themselves. There was an introduction between me and Mr. Whitehill, and I think Amy, Ms. Quezon, helped with the introduction.
So it wasn't where I took a roll call or notes, so I'm not sure, but I believe those people at some point might have been on the conversation.
Q. Were you ever on --
I'm sorry, I didn't mean to interrupt.
A. No, that's okay.
Q. Were you ever on the phone with any of the other experts in the case or in a

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meeting with any of the other experts in the case where there weren't also at least one plaintiffs' lawyer there?

A. So, I know you -- we aren't agreeing on the term "meeting." There were some periods of time where I was reviewing depositions and James Geldhof was also tasked with doing -- reading depositions.

So we would review depositions and then once a week we would meet and we would compare our review of those depositions. And at the conclusion we put a product together to send to the attorneys. I would put a product together.

Q. So you were working with Mr. Geldhof on your report?

A. It wasn't on my report at that time. I hadn't really started writing my report because the discovery material, really, wasn't available -- I don't know if it was in, but it wasn't available to me. But the depositions were underway. And actually, I wasn't even aware they were underway.

I remember receiving a phone

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call and kind of asked what I was doing, and I said nothing. I hadn't heard from the plaintiffs in a couple of months during the summer months, which I wasn't complaining about because I was enjoying my summer. And then they said they wanted to start sending depositions and for me to review them. So then boxes started to arrive at my house.

I immediately knew that I would never be able to read all of the depositions, so I started with one particular company and started reviewing those depositions.

Mr. Geldhof had already -- he was a lot more diligent than me in reading the depositions. So the ones that we both read, it wasn't like a concerted effort; we would just meet and discuss our review of the depositions.

Q. All I'm really trying to understand is whether, for your report, you had anyone else working with you or for you, whether it's Mr. Geldhof or anyone else?

A. No, sir. No, sir. The only person I had those discussions with was Mr. Geldhof. Now, he may have seen something

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in a deposition that I missed or didn't bring to my attention, so I would go back, take some notes, review the deposition myself, and either find that it was useful and incorporate it, or dismiss it.

Q. In connection with putting together your report, did you speak with anyone or interview anyone from Summit or Cuyahoga County?

A. No, sir.

Q. Did you visit any pharmacies in Cuyahoga or Summit County in connection with putting your report together?

A. No, sir, I did not visit any pharmacies.

Q. Okay. Did you spend any time in Cuyahoga or Summit County at all in connection with putting together your report?

A. Well, in a broad sense I'd have to answer yes, and that's because I attended some of the court hearings at the request of the plaintiffs' attorneys, so I was able to hear some of the presentations that were made, which I guess would be useful in some ways of guiding me.

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I wasn't -- I don't think I was requested to be there for that particular purpose to use that information, but I think any information that I received in regards to this report and -- I keep calling it investigation -- my evaluation, was impactful in crafting my report.

Q. Which -- do you remember which court hearings you went to?

A. I went to the one, and I don't remember the date, I'm sorry, where Mr. Rannazzisi testified, and there was a document presented on behalf of the DEA. I think it was -- it was a large hearing. I know that.

Q. I remember it.

A. Okay. I was there.

Q. I was there, too.

A. Only because they made me sit up at the very front, which I wasn't very comfortable with.

Q. Well, get used to it. You may have to testify in the case, you know.

A. Well, I know. I understand that, but when everyone's in the courtroom

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and you're told to sit up here in the front, kind of in front of the jury box, I was a little nervous up there.
Q. And did you go to any other hearings?
A. No, sir.
Q. Okay. So did you review any of the deposition transcripts of any of the Summit or Cuyahoga County officials?
A. No, sir.
Q. Okay. Did you ask for them?
A. No, sir.
Q. Did the plaintiffs' lawyers send them to you?
A. I have numerous boxes of depositions at my house that I haven't went through them all, so I can't answer one way or another if one of them may be in there. So I have to say I don't know.
Q. Do you know who Demetra Ashley is?
A. I do.
Q. Did you overlap with her at all in Detroit? Because she worked in Detroit as well.

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A. So during -- we hadn't discussed this, but during my career as a Romulus police officer, I was actually a sergeant, I was head of a narcotics unit for the city police department. So in the course of some narcotic investigations, I got an invitation from the DEA to become a task force officer.
So I left my department for a period of about -- almost five years and worked in the capacity that would be similar to an agent, which is different than a diversion investigator.
I believe she was there then. I'm pretty sure she was there then, so if I met her, it was just casually.
My only recollection -- to be honest with you, I didn't know that diversion even existed in my law enforcement career, and -- not that I want to digress, but they would destroy drugs once a month, so I'd come to work and everybody would be in the hallway just getting rid of cough syrup and there would be this awful smell. And it would be like kind of a joke that day, on drug

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destruction day. And I'm sure that I met her in that time period.
Q. Okay. And are you aware that there came a time in 2015 when she actually moved into one of the top positions at the DEA?
A. Yes, sir.
Q. In fact, she and Mr. Milione kind of replaced Mr. Rannazzisi. You knew that, right?
A. Yeah, so -- and I don't know if this would be something that your question -- that I should have answered previously. She was in her capacity near the end of my career where one of my cases, there was negotiations, and she -- or discussions about the case, and she was part of those discussions.
Q. Okay. You did not -- your report doesn't say that you reviewed her deposition either. Did you review her deposition?
A. I started to review it, but I would probably say maybe the first 20 pages.
Q. Just 20 pages?

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A. I think so.
Q. Okay.
A. Maybe a few more, but I did not read the full deposition.
Q. Okay. Thank you for all that.
A. Yep, you're welcome, sir.
Q. I apologize for taking so much time on this background stuff, but someone's got to do it.
A. I understand.
Q. Are you familiar with the regulation that discusses suspicious orders, regulation 1301.74, subpart (b)?
A. Yes, sir.
Q. All right. And does that regulation define suspicious orders?
A. I think the regulation itself is a broad regulation and, I think, for a good purpose. I think it gives some guidance on a suspicious order, but I think the actual full definition is up to the registrant, depending on a lot of factors; the scope of their business and the scope of those customers that receive products from them.
So I think -- I know there's a

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lot of criticism about the -- or there's some criticism about the regulation. I think it's a perfect regulation for industry to adhere a specific program to.

Q. The regulation defines suspicious orders as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency; is that correct?

A. Well, that is what the regulation says, but -- but I'm not so sure I agree if you're saying the word "defines" says that suspicious orders could only be those things.

I think that's up to the registrant to -- because there could be other factors where a suspicious order could be identified other than those three parameters.

Q. Does the order tell the registrant what is meant by an order of unusual size?

MR. FULLER: Form.

A. No, I think that's up for the registrant to define based on their application of their maintenance of effective

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controls. You know, that question has come up before. I think the important thing first for a company or a registrant is define what "usual" is, and that would be their due diligence and their maintenance of effective controls.

Many companies focus on trying to define an unusual order when they don't sufficiently understand what a usual order is in regards to what kind of business they're operating and the scope of their business.

MR. FULLER: Bob, and not to pick on your flow, but your last question was does the order tell the registrant.

MR. NICHOLAS: Oh, my mistake.

MR. FULLER: That's why I objected.

MR. NICHOLAS: I appreciate it. Well, then I appreciate it.

MR. FULLER: But Rafalski still answered it.

MR. NICHOLAS: That's fine.

THE WITNESS: I thought I had to.

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MR. FULLER: No, but he asked does the order tell the registrant.

THE WITNESS: I'm sorry.

MR. FULLER: But you meant the regulation.

MR. NICHOLAS: Yeah.

MR. FULLER: Fair enough.

THE WITNESS: So is my answer correct? I mean, not correct. Was it on point? I'll take it back.

MR. NICHOLAS: We're going to sync up your answer with my screwed-up question with the correction, and it's going to work.

THE WITNESS: Sorry.

BY MR. NICHOLAS:

Q. So is it fair to say that the determination as to whether an order is of unusual size is a subjective determination?

A. No, I don't think so. Generally speaking, I think if -- hypothetically, I think that if a company, especially a large company, has sufficient -- sufficient data that they can come up with a reasonable, usual amount that a customer

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would be expected to purchase, and I think that a purchase that would exceed that as a system that would trigger that order to be of unusual size, I don't think that's a subjective nature.

Certainly, I guess companies could just hire people to just look at orders and then say that's an unusual order and that would be more of a subjective, but I think any system that's designed takes the subjective nature out of it.

Now, subsequent decisions may be subjective, but the actual identification would not be.

Q. What do you mean by "subsequent decisions"?

A. So an order is -- triggers as unusual order based on the size, and then the company has a couple of decisions to make. One, and this is based on my experience and based on the Masters case, is they could report it to the DEA and then not ship it and that could be the end of it.

So if they want to make a determination on whether or not they want to

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ship it, they have to dispel the fact that it's a suspicious order to make sure that it's not diverted.

So someone obviously would have to gather some facts, and I guess make an evaluation of those facts. So what facts that that person, he or she, gathers and their opinion on whether or not it's suspicious, I think there has to be some level of subjectivity in there.

You could have a checklist and you could have a lot of formal procedures, but ultimately, someone has to make some decision.

Q. I would ask you the same question about orders that deviate substantially from a normal pattern. Is the determination of whether orders deviate substantially from a normal pattern a subjective determination?

A. My answer is kind of going to run parallel to the size. I think an unusual pattern start -- you know, first a company has to establish what's a usual pattern.

In regards to the preparation

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of my report and review of the policies, one of the most common patterns -- well, I wouldn't say common, but one pattern that some companies elect to look at are the relationship between the purchase of controls and noncontrols.

So they can establish with their own records what would be a normal range of noncontrols related to controls. So any change in the purchasing of that would be an example of an unusual pattern.

Another one that some companies in my preparation of my report would be cash payments versus insurance payments, so that a change in the percentage there. That would, of course, only occur if the companies were diligent, asked that question on a periodic basis.

There are many other patterns that are overlooked in my preparation of the report by companies. One of the easiest would be companies generally seem to be looking at drugs as families, and what I mean by that is lumping all the oxycodone products into one family or by their drug code.

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So within those families, there's -- my experience in doing these cases is there's generally a hierarchy of drugs where some drugs are ordered more often than others. They're just generally prescribed more.

So during the course of when a potential diversion would occur, there could be one strength of drug which actually occurred -- which really impacted what happened in America -- the oxycodone 30 product became a highly abused product. So companies should or would want to monitor within that drug family if there was a change in pattern where one drug started to get ordered in a much greater amount than the other drugs.

Along those same lines, another pattern is how companies order drugs. Typically in the old days they used DEA Form 222s. That's a paper form with ten lines. Some companies generally order drugs in the same manner.

I've reviewed countless number of forms, and as you go through the forms day

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by day, you'll see patterns on how drugs are ordered, certain groups together. In the cases I've worked, when that pattern changes, so an easy one would be all of a sudden you see an order form with ten lines and all ten lines have oxycodone 30. If a company would start to change a pattern of orders like that, that would be an easy one.

Q. Is it also possible that patterns or size or frequency can change suddenly based on changed circumstances in a particular community?

A. Sure, anything is possible.

Q. Well, I don't just mean anything is possible. I mean, yes, anything is possible, but I'd like to be a little more specific.

A. Okay.

Q. Let's say -- let's say a hospital opens up in an area. Would that change patterns and could it change ordering patterns and size of orders and frequency of orders?

A. Well, I think that obviously has a possibility to cause some change. I'm

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not sure that it would change the pattern. It may change the amounts or the types. So another -- as was one of my examples, the types could change.

Anytime a business model changes or a new contract -- a better example, if I could give you a better example.

Q. Sure.

A. Is a pharmacy could enter into a contract with a long-term care facility, and if they didn't provide guidance or information to their distributor, they could just start ordering a controlled substance that would be out of the norm of something they ever ordered before.

That's kind of the essence of the suspicious order system because you would hope the system would trigger to stop that order. Then it requires some due diligence where a company would actually call and they would learn about that contract. And then subsequent to that, the distributor or the person making the sale would probably confirm that that actual contract occurred and that

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business relationship occurred.

So...

Q. So patterns can change?

A. Sure.

Q. Size can -- you know, unusual size can change. Frequency can change depending on the circumstances that occur in a particular community, right?

A. I've learned in my experience that the ordering and distribution of drugs is not static. It's heavily patterned, especially the more the customers, the more the established pattern, sizes and frequency. But new drugs could be introduced.

There's a lot of reasons why it could change. And that's not a bad thing, but those are the things that would trigger your system to stop an order and then you to evaluate it to make sure that -- not you personally, but so that it's evaluated, and then there's no chance of diversion.

Q. So while that investigation is going on, you're saying that those drugs should not be shipped to a place where let's say there's a new -- a new long-term facility

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in town or a pharmacy has a relationship with a new long-term facility? You would stop shipment of those drugs?

A. I think that's what the regulation calls for, yes, sir.

Q. Okay.

A. Well, not the regulation, but the maintenance of effective controls. Because to just go ahead and make shipment without confirming that diversion is occurring, I think the flipside of your question is probably, you know, just as drastic, to allow drugs to go for a purpose when you've already identified that there's the potential for diversion.

Q. I mean, it's also drastic if drugs are not going to people who need them, correct?

A. That's correct, but in most cases, the drugs we're talking about -- well, let me stop to answer that way.

First, the situation would be as I would hope that companies would take into account -- or not that they would have to clear that order in a reasonable amount of

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time, we're not discussing weeks or months. And I certainly don't speak for the companies, but I'm certain that they act in a fairly quick manner to resolve that. And, you know, I'm not so sure that the drugs we're talking about are -- in a long-term care facility would be life-threatening, but I'm not a doctor, so -- but just generally speaking through my experience.

Q. I guess I should have asked you at the beginning. You're not a licensed physician, are you?

A. I am not.

Q. You're not a pharmacist, right?

A. I am not.

Q. Okay. But it is correct, isn't it, that the drugs we're talking about, opioids, do serve an important medical purpose, correct?

A. Absolutely. I think there's a segment of the population in America that need those drugs.

And I think that's an important question and an important answer because, you know, through my career there's a lot of

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accusations that the DEA works to impede that, and I find that far from the truth. I mean, the number one goal as far as I'm concerned and in our mission statement is to make sure that there's an uninterrupted supply to those people who need those drugs.

Q. And sometimes those people need those drugs because they are terminally ill and have a limited amount of time to live and are in tremendous pain in their last days, right?

A. There's all --

MR. FULLER: Form, scope.

MR. NICHOLAS: Go ahead.

A. Sure. There's all kinds of reasons why those drugs are a necessity to people that have a medical need for them. I agree.

BY MR. NICHOLAS:

Q. Okay. I'm going to ask you just a few questions, not many, about three, four pages in your report, pages 10 to 13, in which you discuss something called Discovery Ruling 12.

A. Yes, sir.

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Q. Do you remember that? Do you know what I'm talking about?

A. Yes, sir.

Q. Okay. And this is a discovery ruling that was issued by Special Master Cohen; is that right?

A. Yes, sir, in regards to the Masters Pharmaceuticals case.

Q. And you understand that the Special Master's role in the litigation is to address discovery issues, right?

A. Generally speaking, yes, sir.

Q. Okay. And he is not -- he's great, but he's not the judge, right?

A. Understood.

Q. Okay. And he's not the jury either.

A. Understood. I -- so I think that's one of his roles. I only -- I say that because when I read some of the depositions, I see there's some conversation back and forth about we may have to call Cohen, so I think he maybe makes rulings in regards to deposition matters too.

Q. Yeah, and that's part of the discovery process.

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A. Oh, discovery process, okay.

Q. Depositions are part of discovery.

A. Understood. Okay.

Q. Now, when you discussed his ruling, you put four pages in the report on his ruling. How did you know to do that? I mean, how did you even know that that thing existed? Who told you about that?

A. It was provided to me by the plaintiffs' attorneys.

Q. Okay. And what did they give you? Did they give you his ruling?

A. Yes, sir.

Q. Okay. And so is it your position that his ruling is the -- the -- states the law with regard to the regulatory obligations of the various defendants in this case?

A. Well, my understanding is his ruling kind of breaks down the Masters Pharmaceutical case and the appellate court decision that resulted from that case, and he kind of gives a general understanding of what

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my -- my section was the suspicious order system, how it works, the reasonableness of it, and the maintenance of effective controls. And his was an interpretation.

Q. An interpretation?

A. Of -- well, I wouldn't say an interpretation because obviously he's not going to interpret the appellate court ruling. I think it's kind of a common sense or just kind of a good written product of the Masters Pharmaceutical case. That was my investigation.

Q. And so you referenced Discovery Ruling 12, and then I didn't see any reference to his next ruling on this motion, which had to do with withdrawing a portion of Discovery Ruling 12.

Do you remember that?

A. I don't think I reviewed that. I wasn't provided that.

Q. Okay. So you weren't provided with Special Master Cohen's follow-up ruling on Discovery Ruling 12, correct?

A. I do not recall that.

Q. And you wouldn't have known

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about it -- I mean, you wouldn't have known to ask for it because you didn't know it existed, right?
A. Right. I was provided so many documents, I don't have any recollection of reviewing it. But I'd like to leave the slim chance that maybe I did and I just don't recall. I know it's not referenced in my report.
Q. Right. Okay. So maybe there's a slim chance. I didn't see it in any of the documents.
A. Well, you know what, I'm drawing a blank on that particular, but there is a possibility that I guess at some point. I get so many of these documents that it may have been provided to me.
Q. Okay. So you don't know that Special Master Cohen wrote that his -- and I'm just reading from his follow-up report, which you have -- his follow-up ruling, which you did not see: Second, the discourse was not meant to be authoritative or conclusive on how all suspicious order monitoring systems must work. As distributors note,

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resolution of whether their SOMS met applicable legal requirements over time is a question for another day.
So you didn't see that?
MR. FULLER: Form.
A. No.
BY MR. NICHOLAS:
Q. Okay. And you didn't --
A. So -- I'm sorry.
Q. Well, I just want to know whether you remember seeing that.
MR. FULLER: You can finish answering that question. Go ahead.
MR. NICHOLAS: Yeah.
A. I don't remember seeing that particular statement.
BY MR. NICHOLAS:
Q. Okay. And so you also don't remember -- or do you remember seeing this statement: In sum, distributors are correct that Discovery Ruling No. 12 was exactly that, a discovery ruling, and not a definitive pronouncement on their legal obligations.
Do you remember seeing that?

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MR. FULLER: Form.
A. I do not recall seeing that.
MR. NICHOLAS: Okay. Let's take our first break, if that's okay. Five minutes.
THE VIDEOGRAPHER: Going off the record, 10:26 a.m.
(Recess taken, 10:26 a.m. to 10:38 a.m.)
THE VIDEOGRAPHER: We're back on the record. The time is 10:39 a.m.
BY MR. NICHOLAS:
Q. Mr. Rafalski, it's correct, isn't it, that there was a time when the DEA approved suspicious order monitoring programs, correct?
A. Sir, I'm never aware of any time where there was an approval of a particular system.
Q. Okay. If there was ever an approval of a particular system, that would be like highly relevant information, right?
A. Well, it could be, but I'm just testifying from my review of records and my experience, mainly my expertise and my

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training with the DEA where it's clearly stated from the day I was employed that the DEA doesn't approve systems.
Q. Okay. Did you ever review any documents in this case that have been produced in the case having to do with AmerisourceBergen's suspicious order monitoring system?
A. I'm sure I did in the preparation of my report. If you want to -- is there a particular document that you want to...
Q. There is.
MR. NICHOLAS: Let me start with -- let me start with Tab 17. So just for everybody's information, we have -- we didn't bring like 20 of these things, all right, but I have one for the witness. I have one for me. I have one for Mr. Fuller and then what do we have? Maybe one other? We have six copies. The rest of you guys can share.
MR. FULLER: They're stickers. You just peel them off and put them

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on.
MR. NICHOLAS: Okay.
(Whereupon, Deposition Exhibit Rafalski-1, 9/30/96 Zimmerman Letter ABDCMDL00215791 - ABDCMDL00315794, was marked for identification.)
BY MR. NICHOLAS:
Q. You can take a look at this. This is a letter written -- dated September 30th, 1996. It's on Bergen Brunswig Corporation letterhead. Now, Bergen Brunswig was the predecessor company for AmerisourceBergen. You knew that, right?
A. Yes, sir.
Q. Okay. So Mr. Zimmerman writes this letter, Chris Zimmerman. Did you ever meet Mr. Zimmerman before?
A. No, sir.
Q. Okay. And he's been with the company for many years, involved with their suspicious order monitoring program. And you see he's written a letter to Thomas Gitchel, who's the chief of liaison and policy section for the DEA, the Unites States Department of Justice.

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Do you see that?
A. Yes, sir.
Q. And you can see from this letter that he is introducing to the DEA a new system under development by Bergen Brunswig Drug Corporation to monitor and report customer orders of controlled substances which fit the suspicious order criteria outlined in 21 CFR, Section 1301.74(b).
Do you see that?
A. I do.
Q. Okay. And you can take a minute to review the report -- to review the letter if you need to, but let me start by asking you: Have you seen this letter before?
A. I believe I have.
Q. Okay. Then so you recall its contents?
A. No, I'd like an opportunity to read it, if I could have a minute or two.
Q. Sure, why don't you take a minute to look at it.
(Document review.)

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A. Can I ask a question about the document? It seems I have a recollection that there were other documents before and after this document.
BY MR. NICHOLAS:
Q. I'm going to show you each -- I'm going to show you all the documents I have. I'm going to show you the documents I have.
A. Okay.
Q. Yeah. Okay. You ready?
A. Yeah, I'm ready.
Q. All right. So Mr. Zimmerman wrote to the DEA and explained that AmerisourceBergen would like to go to a new enhanced program for the monitoring and reporting of customer orders, right?
A. Say that question one more time, sir.
Q. Mr. Zimmerman was writing to the DEA to seek permission to replace Amerisource -- to replace Brunswig -- Bergen Brunswig's current -- let me start again.
Mr. Zimmerman was writing to the DEA to express -- to request permission

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to replace Bergen Brunswig's current manner of daily suspicious order reporting with a new daily electronic facsimile report, right?
A. Yes. So if I understand this correctly, and part of my answer I think is my recollection of the other documents, is the crux of the conversation is the authorization to provide them in an electronic or facsimile manner, and not in regards specifically to the system. If that's my recollection -- but that's taking into account some other documents.
Q. Well, let's look at page 2 of the letter.
A. Sure.
Q. Mr. Zimmerman writes: Our plan involves the creation of a computer program that compares a customer's controlled substance orders (expressed in metric units of the active ingredient) against a standard representing an average of the customer's prior four months of orders. Customers whose orders exceed by a specified percentage their prior four-month average order history would be printed on a summary report.

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BBDC's mainframe computer in Orange, California would automatically fax this report simultaneously to each respective DEA field office daily in the early AM hours after the distribution center has completed order processing review.

When DEA offices open each day, the summary report will be waiting for their review. DEA offices could also elect to receive a month-end version of this report via US mail.

Do you see that?

A. Uh-huh.

MR. FULLER: Form.

A. Yes.

BY MR. NICHOLAS:

Q. So it's more than --

A. Yes. I don't -- yes, sir. I don't want to say uh-huh. I'm sorry.

Q. That's okay.

So it -- this also describes exactly what standard would be used. It describes a four-month average to be sent to the DEA, correct?

MR. FULLER: Form, misstates

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the document.

A. This -- I guess your statement is what this document says.

BY MR. NICHOLAS:

Q. Uh-huh.

A. But I think the purpose of the document is asking for the method to turn the -- send these reports to the DEA. I don't think it's asking for approval or guidance on the suspicious order system. I think it's just an advisory of what the company, I think at the beginning, says that they're under development. So I'm not sure this is exactly what they are going to do.

But again, because there were other documents, I'm pretty sure this started out with just changing how they sent these reports to the DEA.

Q. I also wanted to show you, like if you go a couple of paragraphs up, it says -- Mr. Zimmerman says: I can appreciate DEA's belief that 12,000 BBDC telephone calls per year may be, quote, overdoing it, if not for the fact that the regulations clearly place the responsibility solely on the

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registrant to disclose any orders which fit the suspicious order criteria, and it has always been BBDC's position to adopt a conservative and thorough approach on matters involving controlled substance regulatory compliance.

So were you aware that at this point of time in 1996, as of 1996, Bergen Brunswig was telephoning the DEA, DEA field offices, 12,000 -- 12,000 times a year to report excessive purchase orders or suspicious orders?

Did you know that?

A. No, sir.

Q. Okay. And was there anything -- is there anything in your mind that was wrong with that?

A. Well, that's a pretty broad question. Which --

Q. Well, just --

A. Calling 12,000 times a year?

Q. Yeah.

A. If a registrant has any type of system that requires contact with the DEA 12,000 times a year, I think -- and without

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having the full information of the system, I would say that there's a problem with that system.

Q. Does that mean -- well, what do you mean by -- do you mean that if a system is -- if a system -- do you mean that there should not be 12,000 suspicious order reports a year?

A. I'm not saying whether there should or not. What I'm saying is that when I see the number 12,000, that would bear for me, if I was aware of that, it would bear some scrutiny because it would seem like --

Q. It's a lot.

A. Yes, extremely large number on a yearly basis. 365 days a year, I guess how many customers, it's -- if you average it out, that's a large amount of calls every day to call the DEA.

Q. So your expectation is that there really shouldn't be 12,000 suspicious orders reported a year, right?

A. I really don't have an expectation of any particular number, but I think 12,000 would exceed -- in my experience

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and years of doing these investigations, I would find it unusual that there would be 12,000 reports in a year.

Q. Okay. Now, look at the -- look at the end of -- look at page 3 and the second half of the paragraph at the top, where it starts -- where it reads as follows: There are some key questions that DEA would need to provide input on before the report is finalized. One question would be assignment of the percentage value that a customer's order would have to exceed before that order would appear on the report. This value would directly impact the size of the report.

Working with DEA's input, we hopefully will identify the optimum percentage value that will yield DEA the highest quality information without sacrificing administrative cost and efficiency.

Once the field office test is concluded and the recommendations incorporated into the final product, then we can coordinate with your office to introduce the report to the entire DEA system.

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Do you see that?

A. Yes.

Q. Okay. Anything wrong with that?

A. I think there's several things wrong with it.

Q. What's wrong with that?

A. Well, first of all, I don't believe that it's DEA's obligation to provide input or guidance on an optimum percentage value. I think that's a decision that has to be made by the registrant. That's their regulatory obligation.

Q. So just on that, you don't think that Bergen Brunswig should have asked the DEA about this at all?

A. I think they can always submit questions, but I think all registrants throughout many years with interacting with the DEA are aware that the DEA won't give specific answers in regards to thresholds or establishing thresholds or percentages. I think -- let me just read this one more time. There's one more comment I'd like to make.

Q. Sure. Of course.

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A. I guess there's one statement in here where it says: This value would directly impact the size of the report.

So in designing a suspicious order report, the goal is, is to identify suspicious orders, not to try to design it to limit the number of reports or have a design which lessens reports that a registrant would have to submit to the DEA.

Q. Oh, no, I completely agree. Read the next sentence. You can read it out loud.

A. It says -- well, let me read the first one: This value would directly impact the size of the report. Working with DEA's input, we hopefully will identify the optimum percentage value that will yield DEA the highest quality information without sacrificing administrative cost and efficiency.

Q. Is there anything wrong with trying to work with the DEA to yield the highest quality information without sacrificing administrative efficiency?

A. Well --

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Q. Is there anything wrong with that?

A. There's nothing wrong.

Q. Okay.

A. But that's a registrant's responsibility under the regulation. I would hope every registrant was designing some system for optimum results.

Q. Well, obviously AmerisourceBergen was trying to do that if you read this, right?

A. Well, I think that's their regulatory responsibility.

Q. And they were doing it, right?

A. Well, they're attempting to do it.

Q. They were attempting to do it, okay. And they were asking the DEA to work with them, correct?

A. But I'm going to restate again that it's --

Q. I'm just asking whether they were asking. Were they asking?

A. They were --

MR. FULLER: Let him finish his

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answer. Let him finish his answer, Counsel.
MR. NICHOLAS: Okay.
BY MR. NICHOLAS:
Q. Were they asking the DEA to work with them? Yes or no?
MR. FULLER: Form.
A. Well, it's not a yes-or-no question. They were making the request from the DEA, but by making that request, these companies -- or this company probably had, most likely, knowledge that the DEA doesn't give guidance on how to specifically design a system. That's up to the registrant.
MR. NICHOLAS: Okay. Let's go to Tab 19. We'll make this Exhibit 2.
MR. FULLER: When you say Tab 19 --
MR. NICHOLAS: I'm sorry. I'm talking to Abby over here.
MR. FULLER: Got it.
MR. NICHOLAS: We've got these things in our own peculiar order.
(Whereupon, Deposition Exhibit Rafalski-2, 10/29/96 Gitchel Letter,

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ABDCMDL00315789 - ABDCMDL00315790, was marked for identification.)
BY MR. NICHOLAS:
Q. You can take a look at this letter.
(Document review.)
MR. FULLER: Is this Exhibit 2?
MR. NICHOLAS: Exhibit 2.
BY MR. NICHOLAS:
Q. Okay. So Exhibit 2 --
A. Go ahead, sir.
Q. You've reviewed it. So Exhibit 2 is a letter back to Mr. Zimmerman from Mr. Gitchel, the chief of liaison and policy section, Office of Diversion Control for the DEA. It's dated October 29th -- at least it's stamped October -- well, it was received on November 4th, 1996. Let's put it that way.
And Mr. Gitchel says a number of things that I would like to ask you about. First of all, I see he didn't shut down the request, correct?
MR. FULLER: Form.
A. Could you clarify what request

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you're speaking of? The --
BY MR. NICHOLAS:
Q. The request to --
A. To facsimile -- to change how the reporting goes?
Q. He didn't shut down the request for permission to change their suspicious order monitoring program. He didn't shut it down, right?
MR. FULLER: Form.
A. I could see where you could draw this conclusion from this letter.
BY MR. NICHOLAS:
Q. Okay. Let's look at the second paragraph. We've reviewed your proposal -- I'm reading from it -- and feel that it could be a viable alternative to the current system. It is our understanding that a computer program has been created that can compare a customer's controlled substance orders to an average of the customer's orders for the prior four months. Customers' orders that exceed their four-month average order history by an as-yet-unspecified percentage, would be shown on a summary report that would

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be sent to the appropriate Drug Enforcement Administration (DEA) field office on a daily basis.
As proposed, the summary report would include the customer's name, address and DEA number, a description of the item ordered, the NDC number, date ordered, active ingredient, volume ordered and shipped, and the customer's allowance or average order.
Do you see that?
A. Yes, sir.
Q. Okay. So a couple of things about this.
First of all, Mr. Gitchel is summarizing here the fact that customers' order -- he repeats that customers' orders that exceed their four-month average order history by an as-yet-unspecified percentage would be shown on the report, correct?
A. Yes, sir.
Q. Okay. It's interesting because this last sentence also says: As proposed, the summary report would include the customer's name, address and DEA number, a description of the item ordered, the NDC

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number, date ordered, active ingredient, volume ordered and shipped, and the customer's, quote, allowance or average order.

You see that sentence?

A. Yes, sir, I see that sentence.

Q. Okay. So Mr. Gitchel understood that these suspicious orders were being shipped, didn't he?

A. Well, I can't comment on what Mr. Gitchel thought about the letter. I can -- I can make some comment about the -- what was written here.

I'm not sure that it's clear to me that that paragraph describes suspicious orders.

Q. Okay.

A. That -- meaning that Mr. Gitchel is making a comment that this is in compliance with 1301.74(b).

Q. Do you have any question that Mr. Gitchel understood that orders that are being reported to the DEA are being shipped?

A. That's what this paragraph says, yes.

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Q. Yeah.

A. Yes.

Q. Okay.

A. So I'm just going to restate: In this paragraph, this particular paragraph, I'm not -- my answer when I say that's what the paragraph says, I'm not trying to indicate what Mr. Gitchel believed he -- what his thoughts were on whether he wrote this paragraph, whether those were, in fact, suspicious orders.

Could have been some other kind of a database that was being provided to the DEA. I mean, it's 1996. I think -- I don't really have a comment on Mr. Gitchel's beliefs.

Q. Things were different in 1996, weren't they?

MR. FULLER: Form.

BY MR. NICHOLAS:

Q. You just said it. It was 1996.

A. Well, it's a long time ago. Only because I don't have knowledge of something that occurred in 1996. I would say that the regulation was exactly the same in

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1996, and the DEA's interpretation of the regulation in 1996 was the same as it is today and even previous to this date.

Q. Well, if it was the same as it is today, why in 1996 was the DEA saying -- why was the DEA acknowledging right in its letter that it understood that customer orders that exceed their four-month average order history would be sent to the appropriate DEA field office; the summary report of those orders would -- would include certain information, including when those orders were shipped?

I mean, are you really saying to me that it is not clear to you that the DEA understood in 1996 that orders that were reported as either excessive or suspicious, whatever word you want to use, were being shipped? Is that your testimony, having read this paragraph?

A. We can read it again. My testimony would be as, first of all, I'm not going to make a comment on what Mr. Gitchel believed this paragraph actually complied to. If it was some kind of a database submission,

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I know there was excessive purchase reports being submitted to the DEA at that time.

I know the first sentence in the next paragraph is: We note that unlike the program that generates Bergen Brunswig's monthly suspicious order report -- which would differentiate that this paragraph might be speaking to a different topic than the first statement -- first sentence of the next paragraph.

So I'm just -- I don't think it's possible for me to make a comment on this communication by just looking at this letter.

Q. Okay.

A. I'm not going to disagree that that's what that paragraph says, because it's written words.

Q. It is written words, and maybe we'll just have to let the words speak for themselves.

A. I think we will. Or Mr. Gitchel.

Q. Yeah. Well, I think he has.

Now, you'll see that

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Mr. Gitchel has gone ahead and said in this letter, in the next paragraph -- the last sentence of the next paragraph says: It is therefore requested that each DEA office continue to be provided with the monthly reports in addition to the daily facsimile reports.

It would also be helpful to our investigators if the quantity of drugs ordered were expressed in dosage units rather than by the weight of the active ingredient.

So Mr. Gitchel is clearly engaging with Mr. Zimmerman and there's a dialogue about what the DEA would like to see in these reports, correct?

MR. FULLER: Form.

A. I would agree, that's what this letter says.

BY MR. NICHOLAS:

Q. Okay. Now --

A. Can I also just make a clarification?

Q. Of course.

A. So when I look at this letter and I read the content and I -- of what

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Mr. Gitchel wrote, I just want to bring to your attention, and you may know that in '96 the DEA had a DEA investigator's handbook, and there was a clear statement in '96 of what the expectation was of a suspicious order report, and this particular -- if what you're saying is you think that Mr. Gitchel is accepting this, that would be in conflict with that investigator's manual.

Q. That manual that you're talking about, that's not a publicly available manual, right?

A. Well, I think it was released out to the public.

Q. I don't think all of it was. It was, in fact, as recently -- as recently as this litigation, the plaintiffs' lawyers tried to prevent the manual from being produced in discovery, so I don't think the whole thing is public even now.

MR. FULLER: That's not true. And actually, Cardinal did have a complete version of the '96 manual that was in their production, as well as other defendants.

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So object to form.

MR. EPPICH: I'll object to that representation. I don't know that that's true, Mr. Fuller.

MR. NICHOLAS: Anyway, we can move on.

THE WITNESS: Yeah, I don't know if there's a question pending. If there is, I need it --

MR. NICHOLAS: Not the biggest point in the world. I was really just bickering back and forth with you because you said something, so I'm going to --

THE WITNESS: I don't want to bicker. I just want to give you some facts.

MR. NICHOLAS: I know. I'm self-correcting.

THE WITNESS: I apologize if I engaged in bickering.

MR. NICHOLAS: As do I.

BY MR. NICHOLAS:

Q. Look at the last -- the last sentence on the page, which says: We agree

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that it would be prudent to test this new program before instituting it nationwide and concur with your suggestion to use the DEA Los Angeles division office for the beta test.

Do you see that?

A. Yes. I see that's a statement, yes, sir.

Q. So -- well, you see it's a statement. Reading it, what do you think it means?

A. I think it means whatever this new system that AmerisourceBergen is talking about, or Bergen Brunswig Corporation is talking about, and they're going to implement whatever they intend to give to the DEA, Mr. Gitchel is telling them to run a test on the program before he institutes it nationwide, which is pretty typical guidance that any registrant would receive from the DEA anytime that they're going to design a system or change a system.

In my experience of doing investigations and looking at records, companies generally always run some -- I

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guess they call it beta test, but test the system to make sure that it appears to be operating properly.

I say "appears" because, you know, if it identifies suspicious orders in the new system, generally there should be some kind of due diligence that would tell them whether or not it's actually identifying suspicious orders or it's not.

Q. Now, did you ever see this letter before?

A. I'm not sure. I remember the first letter. I'm not sure if I did or not, sir.

Q. Okay. And you don't think that these two letters were worth -- I mean, you wrote, I don't know, eight, ten pages about AmerisourceBergen in your report, and you talked about their program in 19- -- you know, in the '90s going up to 2007.

You didn't think that this was worth talking about?

A. No, sir.

Q. Okay. That was your decision?

A. Yes, sir.

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Q. You don't remember this letter, so you don't even know if you saw this one.

A. Well, in reading the first letter, I still believe there might be some other communications that start this particular discussion off about just facsimiles versus phone calls. Not that I'm accusing you of not showing me all the documents, but I had a recollection of some other documents.

This one, I'll go back to my previous statement. I'm not really sure what Mr. Gitchel is discussing or approving.

Q. Well, it's clearly more than just facsimiles or phone calls that they're talking about at this point, right?

A. I would have no disagreement that there's discussions outside of that in this letter.

Q. I mean, they're talking about four-month, you know, analysis. They're talking about the content of the report. They're talking about a percentage. They've clearly gone beyond facsimile versus telephone, right?

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A. Well, that's a correct statement, but at this same period, you have to -- and I'm sure you know. You have to recall that there's these excessive purchase reports that are being submitted to the DEA and the voluminous amounts of paper. Even though I wasn't there in '96, I'm aware of that.

So that just makes me wonder what exactly this discussion is about. And I just find it difficult to make comments on it with, you know, I'm not Mr. Gitchel, and I don't know what Mr. Gitchel was trying to do with this letter.

But I do agree that he wrote it and that the words that are on this letter would appear to be Mr. Gitchel's.

Q. We can at least agree on that much.

A. Okay.

Q. And he is -- he's not just some guy. I mean, he's -- at this period of time he is the chief of the liaison and policy section of the Office of Diversion Control, right?

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A. That's what the letter says.

Q. Well, do you --

A. I have no reason to believe that he's not. But I don't know Mr. Gitchel and this was obviously a little before my time.

Q. Yeah.

A. So I don't disagree that's what the letter says.

Q. Now, what happened in your knowledge -- I mean, did the DEA ever actually approve a new program or no? This new program? Or do you not know?

A. I do not know.

Can I make a correction to something I testified earlier?

Q. Yeah.

A. Without going to my report. I believe there is a mention of the four-month average and the fact that the DEA is working with or that AmerisourceBergen said they're working with the DEA, and if you'd like me to go to my report, I can find that area.

Q. That's okay. Let's just -- I want to stick with --

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A. Just -- you characterized that I ignored it, and I'm pretty sure that I have a section in my report about that.
Q. That talks about the four-month average?
A. It mentions it, and I believe it says that the AmerisourceBergen says that they're working with the DEA in regards to a new system that included a statement, the four-month average. How about if I look at my report now?
Q. No, you can go back -- your lawyer can do that with you later. I have another question.
MR. FULLER: No, if you want to go to the report --
THE WITNESS: Well, if --
MR. NICHOLAS: No, no, no.
MR. FULLER: Hold on. You don't ask permission. You go to your report.
THE WITNESS: I'd like to clarify that, so...
MR. NICHOLAS: Okay. Well, looks like you and Mr. Fuller are

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taking over the questioning for a minute, but...
MR. FULLER: Just like any expert, he's allowed to go to his report if he wants to go to his report.
MR. NICHOLAS: Of course. You're going to be able to question him at the end of this thing. You can question him to your heart's desire.
(Document review.)
A. So it's on page 82, the second paragraph.
BY MR. NICHOLAS:
Q. Okay.
A. It says: During the time period of 1998 through 2007, ABDC implemented a new method of calculating threshold. Mr. Zimmerman -- this was part of his deposition --
Q. Yeah, yeah.
A. -- stated ABDC worked on a threshold project with the DEA for a two-year period from 1996 through 1998 to provide DEA with more accurate information.

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Q. Okay. So --
A. And the next statement talks about the four-month rolling average.
So just a clarification that I think you -- we had a discussion back and forth that I discounted the information in that letter, so...
Q. Okay. And so you don't know -- so they worked from 1996 to 1998 you're saying in your report on this new program.
A. I think I'm saying that's what Mr. Zimmerman is saying --
Q. Oh, all right. Okay.
A. -- in his deposition.
Q. Well, now, good news, we have letters that confirm it because we have letters that say it. We don't just have Mr. Zimmerman saying it anymore, correct?
A. I don't mean to be argumentative.
Q. Okay. The point is it really did happen because not only did he say it but there was also correspondence that confirms it, correct?
A. His statement?

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Q. Yeah.
A. Yes, sir.
Q. Okay. Now, you don't know whether the DEA -- whatever happened to this thing, right, whether the DEA ever approved it or not, correct?
A. I have no knowledge, sir.
MR. NICHOLAS: Okay. Let's turn to Tab 20, Exhibit 3.
MR. FULLER: Thank you.
(Whereupon, Deposition Exhibit Rafalski-3, 7/23/98 Good Letter, ABDCMDL00315783, was marked for identification.)
BY MR. NICHOLAS:
Q. Have you read it?
A. I have.
Q. Okay. It's dated -- this is a letter dated, or at least stamped as received, on July 23rd of 1998, so some time has passed since the last correspondence we saw. And it's a letter from -- it's a letter to Mr. Zimmerman.
I should say for the record, Mr. Zimmerman at this time was the director

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of regulatory compliance and security services for the Bergen Brunswig Corporation. That's in his letterhead.

And this letter is written and signed by Patricia M. Good, who is now at this point in time the chief liaison and policy section -- the chief of the liaison and policy section for the Office of Diversion Control.

Do you see that?

A. I see that.

Q. So I guess there was a change in personnel, and Ms. Good is now in this position, correct?

A. You could draw that conclusion since she now signs as the chief, yes.

Q. And do you know who -- do you know her?

A. Just the name, sir, not personally.

Q. Okay. So can you read the first sentence of the letter?

A. This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify

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and report suspicious orders for controlled substances and regulated chemicals as required by the federal regulation.

Q. And read the second sentence.

A. DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion which is not only useful overall but is also responsive to the needs of individual DEA offices.

Q. You are not familiar with this letter?

A. I don't recall seeing this letter, sir.

Q. Can you read the next paragraph, please. It's short.

A. We appreciate the efforts you have undertaken to develop this improved system and apologize for the lengthy approval process. It did not seem appropriate to grant this approval prior to the conclusion of the Suspicious Order Task Force formed as a result of the Methamphetamine Control Act. Thank you for your patience in this matter.

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Q. Is there any doubt in your mind having read this letter that the DEA explicitly and in writing approved Bergen Brunswig's suspicious order monitoring program on a nationwide basis?

MR. FULLER: Form, misstates the letter.

A. Well, I think the content of the letter is open to the interpretation of the reader. I just would go back to, you know, my experience with the DEA and in my training is that the DEA doesn't give approval to systems, and that was the same information that was consistent in the DEA's manual at this time that this letter was issued.

So -- but I do acknowledge the content of this letter.

BY MR. NICHOLAS:

Q. The content of the letter says that the DEA is issuing an approval of a system, right?

A. Well --

MR. FULLER: Form.

A. I don't disagree that that's

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what this letter says when you read it.

BY MR. NICHOLAS:

Q. Yeah.

A. Now, it doesn't say what the system is. It doesn't give -- I mean, it's a brief letter, but there -- I'm not going to dispute the -- grant approval of a request.

I'm not sure -- I'll just leave it at that.

Q. Do you know how long this -- so do you know how long this system that AmerisourceBergen received approval for on this date remained in place?

A. Well, my report. We can go to my report and I can tell you, if you like.

Q. It remained in place until 2007?

A. Well, let me confirm that.

Q. No, you know something --

MR. FULLER: No, no.

MR. NICHOLAS: I'm not asking you --

MR. FULLER: Counsel, you asked. You asked. You asked the question.

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MR. NICHOLAS: Counsel, I'm not asking him to confirm it. You can go back to it and he can do it later. I'm not running clock here like that, so we can keep going and we will keep going.

Just give me one second.

THE WITNESS: Sure.

BY MR. NICHOLAS:

Q. Had you seen this letter before preparing your report, would you have viewed it as relevant information to be included in the report?

A. Well, the opinion that I was offered -- I was requested to make wasn't an analysis of the DEA's actions; it was whether or not the systems in place were effective.

So it wouldn't have changed my opinion on whether the system utilized by AmerisourceBergen met the regulatory compliances.

Q. I didn't ask you whether this letter would change your opinion. I did ask you whether, had you seen this letter, you would have thought it relevant for purposes

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of inclusion in your report. That's my question.

A. I'd like to just stay with my previous comment. Other than by including it or not including it, it wouldn't have changed my opinion on whether the system utilized was effective or met regulatory compliance.

Q. So even though AmerisourceBergen was running a program that was approved by the DEA in 1998, it does not change the -- any -- it does not change your opinion in your report about AmerisourceBergen; is that right?

MR. FULLER: Form, misstates the document.

A. Well, I'd like to go back to my experience as a diversion investigator. It's occurred in my cases, in a couple of my cases, where registrants have received an opinion that approval of a system or comments on suspicious order systems that were not accurate or they probably shouldn't have received.

So I just would go back and say it's a requirement of AmerisourceBergen to

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design a system that meets the regulatory requirements, and it's not dependent on what the DEA says, the guidance.

Again, I'm not being argumentative. The letter speaks for itself, but my opinion in regards is whether or not that system was an effective suspicious order system.

BY MR. NICHOLAS:

Q. Are you saying that Ms. Good and Mr. Gitchel should not have worked with AmerisourceBergen on these issues?

A. I'm not saying any diversion investigator shouldn't work with a registrant. I worked with registrants during my employment on a regular basis. I'm just saying that to give approval or comment, I see many problems to just the four-month rolling average wouldn't have met -- I wouldn't say my standards. It wouldn't have met the regulatory standards based on my experience in doing these cases.

So I see a lot of issues with the letter, but the approval -- it's well known that the -- from the day I started at

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the DEA it's drilled in that you just don't approve suspicious order systems, so it's just outside -- that letter is outside of any conduct that I've ever known for the DEA, going back all the way to a communication I think I read in 1984. I think there was a comment at that time from the policy liaison that said that the DEA doesn't approve suspicious order systems, so...

Q. So Mr. Gitchel missed that part of the manual and that part of the training?

MR. FULLER: Form. There's no letter of approval from Mr. Gitchel, Counsel.

MR. NICHOLAS: Let's start with Mr. Gitchel.

A. I don't know what Mr. Gitchel did or didn't -- I mean, I know what the communication said. I don't know what his intentions are or what his approval and his letter of what he actually was approving. His letter is not clear to me that that approval is of a suspicious order system.

BY MR. NICHOLAS:

Q. How about Ms. Good's letter?

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That's pretty clear, isn't it?
A. Yes, but it doesn't --
MR. FULLER: Form.
THE WITNESS: Sorry.
A. It doesn't -- doesn't clearly -- you know, it's two years later and it doesn't clearly describe what system is in place there.
BY MR. NICHOLAS:
Q. But you're saying she missed the whole part about not -- the DEA not issuing any approvals also, right, because she went ahead and did it?
A. My knowledge of the content of the diversion manual and my training and the documents I've read as far as DEA guidance, I would say that that would be an accurate statement, yes.
Q. Okay. Before we leave that subject, you are familiar with the letters that Mr. Rannazzisi wrote to registrants in 2006 and 2007, right?
A. Yes, sir, I am.
Q. Okay. And I'm going to ask you just to take a look for a very limited

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purpose right now at his December 27th, 2007 letter, which we'll mark, I guess, as Exhibit 4.
(Whereupon, Deposition Exhibit Rafalski-4, 12/27/07 Rannazzisi Letter, ABDCMDL00269685 - ABDCMDL00269694, was marked for identification.)
MR. NICHOLAS: There you go.
THE WITNESS: Thank you.
BY MR. NICHOLAS:
Q. And I'm really only going to ask you about the -- the last sentence of the second full paragraph. You see it?
A. Yes, sir. Would you like me to read it?
Q. Yeah.
A. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders should no longer be taken to mean that DEA approves a specific system.
Q. Now, Mr. Rannazzisi is writing this letter to registrants in 2007, correct?

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A. Yes, sir.
Q. And he says that past communications that could be construed as approval should no longer be taken to mean the DEA approves a specific system.
Do you see that?
A. Yes, sir.
Q. So when he says that these communications should no longer be taken to mean that the DEA approves a specific system, do you agree that prior to this letter, such communications were taken as approvals and the DEA understood that?
MR. FULLER: Form.
A. Well, I'm not sure what Mr. Rannazzisi knew or didn't know when he composed the letter. My interpretation when I read that is it's kind of just a notification to -- you know, to the industry.
I'm aware that -- in my experience that oftentimes you're on-site or you're having contact with a registrant and the registrant makes -- this would be the implicit -- would make some assumptions on what you're saying or what you're approving

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or if you don't find an error, that that -- or a problem, that that means that it's approval.
So the explicit, you know, that's a different situation, so I -- I just think it's just a clarification. I'm not aware that he was specifically talking about any particular communication.
BY MR. NICHOLAS:
Q. It says should no longer be taken.
A. It does say that, yes, sir.
Q. Yeah. So that means that previously he knew that it was being -- that these -- that these communications were being taken as approvals, right?
MR. FULLER: Object to form.
A. I don't know what he thought.
BY MR. NICHOLAS:
Q. Okay.
A. Or if that was his intention with that statement, that he assumed that was occurring.
Q. Well, that's -- I'm just sort of going by the words. That's how it reads,

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isn't it?
A. That's how it reads, but as I testified to earlier, you know, I had several cases where there were comments made or there was understandings made with contacts between registrants and companies where they believed that something was approved or was ordered of them, which was not accurate.
So I'm not -- but I'll just go back and say I'm not exactly sure what Mr. Rannazzisi's intent was with that particular statement. Just it's clear what -- moving forward what his intent was.
Q. Now, Mr. Rannazzisi also sent a letter on September 27th of 2006 to the various registrants, and I'll just read it. I don't even have to mark it. I can just read one sentence from it and ask you whether you agree with it, because it's just a general statement.
The sentence that Mr. Rannazzisi wrote is: DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion.

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Do you agree with that statement that Mr. Rannazzisi made?
MR. FULLER: Form, outside of his scope.
A. Can you read it one more time for me?
BY MR. NICHOLAS:
Q. Yes.
DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion.
A. Well, based on my work on this matter and my review of records and systems, which I didn't have any previous knowledge of previous to when I did that, I would probably disagree with that statement by Mr. Rannazzisi, in looking at the historic failures by the companies to be in compliance with the suspicious order situation -- or regulation and just a general broad maintenance of effective controls to prevent diversion.
MR. NICHOLAS: It's been -- well, let's take a short break. We'll

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go another 45 minutes after that and have lunch, if that's okay.
THE VIDEOGRAPHER: Going off the record, 11:34 a.m.
(Recess taken, 11:34 a.m. to 11:45 a.m.)
THE VIDEOGRAPHER: We're back on the record at 11:45 a.m.
BY MR. NICHOLAS:
Q. The DEA requires the retention of records to be for at least two years; is that correct?
MR. FULLER: Form.
BY MR. NICHOLAS:
Q. By policy?
A. Well, by regulation --
Q. By regulation.
A. -- the requirement is -- and that two-year applies to required records. So within the CFR, there are certain records, examples would be biannual inventories, order forms. Any of the records that are in the records section of the CFR have a two-year retention.
And there's a carve-out that if

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a state has a longer retention period, that the registrant could be subjected to that, but that two years only applies to those certain records that are cited in the CFR.
Q. So -- but the carveout that you're talking about doesn't apply to suspicious order reports, right? That's within the two -- that's subject to the two-year regulation?
MR. FULLER: Form.
A. No. The suspicious order reports aren't part of the two-year retention.
BY MR. NICHOLAS:
Q. They don't have to be retained at all?
A. Well, under my opinion, it would be they would be retained forever.
Q. Right, but, I mean, the regulation doesn't require -- I understand that might be your opinion, but is there any regulation that says they have to be retained for any length of time?
A. I would say the maintenance of effective controls to prevent diversion would

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be applicable to say that they should retain the suspicious order reports or any due diligence related to them.
Q. There are specific sections -- there are specific regulations that address records retention, correct?
A. Yes, sir.
Q. And those --
MR. FULLER: Form.
BY MR. NICHOLAS:
Q. -- regulations identify the categories of records that have to be kept and for how long, correct?
MR. FULLER: Form.
A. The CFR does address that, but those are the required records. For example, there are some records that registrants keep in the course of their business that aren't a required record. So just so we're on the same understanding as to -- the two-year retention is only under those required records; dispensing records for a dispensing doctor, two-year retention; biannual inventories, order forms, those are all part of the required records.

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BY MR. NICHOLAS:
Q. So the things we're talking about now, suspicious order reports or due diligence documents, are not part of the kinds of records that are required to be retained under the CFR and the regulations?
A. Well --
Q. That's a yes or a no.
MR. FULLER: Object to form. He's already testified they were.
MR. NICHOLAS: That's not what he said.
Go ahead.
THE WITNESS: So could you restate the question? I'm sorry.
BY MR. NICHOLAS:
Q. Does the CFR or its regulations require in writing and as identified suspicious order reports?
MR. FULLER: Form.
MR. NICHOLAS: I'll ask it again. It was a crappy question.
BY MR. NICHOLAS:
Q. Does the CFR identify suspicious order reports as among the

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documents that have to be retained for at least two years?
A. I would say yes, under the maintenance of effective controls, but I think there's not a lot of clarity on whether that is essentially a required record.
Q. Does the CFR identify due diligence documents as documents that are required to be retained for at least two years?
A. I'm going to respond the same: Under maintenance of effective controls, I think that requirement requires the retention of due diligence records. The CFR doesn't speak specifically to a due diligence record, but that would be a record that would be maintained within the requirement of that regulation.
Q. For at least two years?
A. Again, my opinion, they should be kept permanently.
Q. No, I'm not asking about your opinion. I'm asking under -- what the requirement is under the law as you understand it.

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A. Under the regulation as I understand it --
Q. Yeah.
A. -- it doesn't speak specifically to due diligence records. So I -- a two-year retention -- if a registrant was to review the CFR, there's no mention of a due diligence record, so I would say it's not two years.
But again, I'd just restate that I would see no reason why they wouldn't retain them indefinitely.
Q. Okay. I just want to go back for one second to when you said several times that -- you talked about your understanding about how the DEA -- or your belief that the DEA does not -- has never given approvals of suspicious order monitoring systems, and you said that the manual said you're not supposed to and all that.
When did you start at the DEA?
A. 2004.
Q. Okay. When you refer to the manuals, to the Diversion Control Manual, you were referring to a manual that you read in

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2004, right? Or after.
A. Well, I -- I was also referring to the manual that I read as part of my opinion in 1996, and my -- and my opinion on the suspicious orders on approval, it's broader than just the manuals. Multiple trainings, my witnessing of a distributor briefing, the comments made in the training provided; also, my review of communication that I believe Mr. Gitchel made in 1984 where he made that statement.
So -- plus my on-the-job training, my -- there's never been a time where I can ever remember that DEA -- there was a comment made to me that the DEA had approved suspicious order systems.
Q. Wait, you reviewed a statement that Mr. Gitchel made in 1984?
A. I don't know if it was a statement. He made -- I believe he was the one who made a written comment to NWDA in regards to a suspicious order reporting program that was worked on way back then, and he made a comment about not being able to approve any specific.

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Q. Is that in your report?
A. I believe it is.
Q. Okay. No, no --
A. No, I'd like to talk to you about it.
Q. I just want to know if it's in your report.
A. Yeah, but --
Q. Is it -- that's a yes or no. You can check to see if it's in your report, yes or no.
A. Well, let me review my report.
MR. NICHOLAS: It's a 200-page report. We can go off the record and stop the clock running during this review.
MR. FULLER: No, we need to stay on the record.
(Document review.)
MR. FULLER: I think it's on page 32.
THE WITNESS: I'm getting there. I don't want to waste time.
(Document review.)
A. So I discussed that

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communication on page 32 of my report.
BY MR. NICHOLAS:
Q. Okay. Hold up. Yeah.
I just want to know -- I mean, all I really wanted to know is did you put in your report that Mr. Gitchel said in 1984 that the DEA doesn't approve --
A. No, I think I may have misspoke. I think it was in regards to stopping shipments of --
Q. Okay.
A. -- orders.
Q. Okay. All right. That's fine.
A. That's why I wanted to review my report, to make sure.
Q. This was an instance where you reviewed your report and found something -- and found something that I agree -- supported my point, so that's good. I should let you review your report more often.
A. Yeah, you tried to stop me. But I just want to be factually correct. It's an important subject.
Q. I appreciate it.
A. And I had a recollection that

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that was discussed, but it was about stopping an order, so...
Q. All right. So since we are talking about sort of what -- since you just sort of brought up the shipping requirement.
A. Yes, sir.
Q. First of all, just so the -- so we've got it on the record, what do you understand -- it's a weird word, because it's a shipping requirement, but it really -- it's a reference to not shipping.
So can you just explain what the shipping requirement is to your understanding?
A. Well, first, I've never -- there's never really been a formal term. A shipping requirement, I don't know if that's an industry term or just somehow got created, but it never was referred to as just a shipping requirement.
I mean, it's -- it's the mere fact that when a company uses a suspicious order system and identifies a suspicious order, they don't ship that order until they dispel the suspicion about it and whether or

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not it's going to be diverted to ensure that gets properly distributed.
Q. Okay. So let me ask a couple of basic questions here.
Does the CFR or the regulations related to the CFR on this subject say anywhere that there is a requirement that distributors not ship suspicious orders?
A. I think they give guidance to distributors under the maintenance of effective controls. Only saying that because if a distributor discovers a suspicious order, to ship it without dispelling the suspicion, that kind of violates the maintenance of effective controls.
So I don't want to say it's just a commonsense interpretation, but to identify something suspicious that is suspicious of diversion and then just shipping it without stopping it and dispelling it, that's at the core of that regulation.
Q. Does the --
A. And the law.
Q. Does the regulation say

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anything about ship -- does the regulation in words, words, say anything about shipping?
A. No, in words, the regulation does -- and just the --
Q. It does or does not?
A. It does not say the word "shipping."
Q. Okay.
A. But again, I go back to the maintenance of effective controls, and secondly, it's been since the day I started at DEA, that's been the interpretation of the DEA, and I think there's been several communications, Mr. Rannazzisi's letters.
Q. Okay.
A. All the way back -- now I can go back to Mr. Gitchel's letter in 1984, about stopping an order because that was the topic that I discussed -- that I confused on your earlier question.
Q. Do you -- is it your testimony that the decision as to whether to ship or not to ship an order that's been reported to the DEA is left to the discretion of the distributor?

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A. So I think the discretion on whether to ship or not ship is solely the decision of the distributor. The DEA doesn't inform a distributor if or when to ship an order or not to ship an order. So the answer to that would be yes.
Q. And if a distributor asks the DEA -- if the distributor came to the DEA and said, we've got this order, we have questions about it, should we ship it or not ship it, the DEA won't answer that question?
A. So I'm not sure that I'm comfortable speaking for the entire DEA, but how I'd like respond to that is through my experience and what has occurred in the past.
So there may be a time when you receive a call from a registrant that may ask a question like that or a similar question, so generally, you can -- first, I would always state there's two -- two situations, and we're just going to talk about suspicious orders -- or, I mean, about distributions.
And first, I'll always state that I can't tell a distributor when to ship or not to ship, but I may ask a lot of

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questions of the distributor that makes it easier for them to make that decision.
Q. Okay.
A. Now, that's my personal experience. I'm not speaking that the entire DEA does that.
Q. Now, you spent some time in your report talking about the Masters decision; is that correct?
A. Yes, sir.
Q. That decision came out in 2017, correct?
A. Yes, sir. Right after I retired.
Q. Although you were on the team that investigated Masters, right?
A. I was. There was no team. It was just me.
Q. Well, then, I want to say there's no I in team, but somehow that doesn't quite fit, but I'd like to say it anyway.
A. Well, I would say that there's always another investigator with me, but it was my case.

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Q. Okay. Now, Masters, your investigation of Masters was of Masters Pharmaceutical, correct?
A. Yes.
Q. It was not -- you were not investigating any other distributors in connection with that, correct?
A. No, that's not actually a correct statement. I would disagree with the statement. During the course of that investigation, there were some -- they call them gray distributions. I don't know, maybe that's an internal DEA. So that would be distributions from Masters to other distributors.
So I -- you know, that didn't lead me personally to investigate other distributors, but it did -- it did cause me to make notifications about other -- to other offices about other distributors.
Q. You did not -- my question to you was: You were only investigating Masters Pharmaceutical, right?
A. Yes, sir.
Q. Okay.

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A. That was the assignment of the investigation.
Q. All right.
A. Maybe I misunderstood your question. I didn't want you to think that I didn't look at any distributions of other -- to other distributors or --
Q. And Masters, the company, ultimately challenged the DEA's findings from your investigation, right?
A. Yes, they did.
Q. And in so doing, they took the case up to the D.C. Circuit, right?
A. Yes, sir.
Q. And the case before the D.C. Circuit was about Masters's system alone, right?
A. Well, I think the factor that caused it to go to the D.C. court was Masters's system and their use of the system, but I think to me, or more importantly, I believe, to the DEA, I think it was a reiteration of what the expectations were of registrants, and because sometimes I see some commenting that that was the -- that's the

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way that the interpretation is moving forward. I believe that's the way the interpretation of the regulations always was, always was in place.
Q. But the issue in Masters was Masters's compliance with its own policies and procedures, right?
MR. FULLER: Objection, form, misstates the case.
A. Well, it's at the core of one of the issues or at the core of the administrative hearing.
BY MR. NICHOLAS:
Q. Masters came out in 2017. Did I ask you that already?
A. It did. I think it was the week after I retired.
Q. That's right. You said that too.
Now, when the Masters decision came out, do you recall that the industry was confused by the decision?
MR. FULLER: Form. How would he know?
A. I'm not aware of any

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information that would make that a true statement.
MR. NICHOLAS: Okay. We'll mark as our next exhibit, Exhibit 5.
(Whereupon, Deposition Exhibit Rafalski-5, 2/6/18 Nicholson Letter, MCKMDL00561146 - MCKMDL00561147, was marked for identification.)
BY MR. NICHOLAS:
Q. And while you're looking at it, I'll just say for the record, this is a letter dated February 6th of 2018 to Demetra Ashley, the acting assistant administrator for Diversion Control Division of the DEA.
It is written -- it is signed by Kevin Nicholson, the vice president for policy -- public policy and regulatory affairs for the National Association of Chain Drug Stores.
(Document review.)
A. Okay. I've read the letter. I've also read this previously.
BY MR. NICHOLAS:
Q. Okay. Does this refresh your memory or cause you to want to change your

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answer about the question of whether industry was confused by the Masters decision?
MR. FULLER: Form.
A. No, it does not.
BY MR. NICHOLAS:
Q. Okay. Can you look at the first paragraph, the second sentence, from the second sentence to the end.
A. Starting with "The National"?
Q. Yeah.
A. Like me to read it?
Q. Yeah, that would be great.
A. The National Association of Chain Drugstores (NACDS), respectfully request that DEA promulgate regulations to affected registrants regarding their suspicious order monitoring regulatory obligations in light of the Masters decision.
We are aware that the DEA has been working on regulations to clarify registrants' responsibilities under 21 CFR 1301.74(b).
We believe the D.C. Circuit's ruling in the Masters case necessarily increases the urgency of DEA's promulgation

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of guidance concerning affected registrants' suspicious order monitoring responsibilities.
Q. Are you aware that the DEA has been working on regulations to clarify registrants' responsibilities under 21 CFR 1301.74(b)?
A. I did review either a document or a deposition, and I don't recall of which, that spoke to this, and I believe there was one document that indicated they were, but another document or a deposition which indicated they no longer were.
So I guess that's kind of an ambiguous answer, but if you were to ask me what I believe is occurring right now, I do not believe they're working on changing 1301.74(b). That would be my opinion.
Q. Are you aware that for a period of time from 2015 to 2019, they were working on a revision to the regulation?
MR. FULLER: Form.
A. I'm not aware of that.
MR. FULLER: Form. And as far as the Touhy compliance, let's just make sure, Mr. Rafalski, that you're

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basing it on information that you gained from this litigation and not your work at the DEA.
BY MR. NICHOLAS:
Q. So you're unaware of this; is that right?
A. That they were working on the regulation?
Q. Yeah.
A. Well, I don't have any direct recollection that someone told me that the DEA is working on this particular regulation, but at the DEA, up in policy, and they're always working on regulations, and it's not something that's communicated to the field. So I just -- I don't really have any knowledge whether they were or weren't.
Q. Well, in your review of all the documents in this case, the documents that you were provided, did you see either a report from the GAO or a summary of a report from the GAO concerning diversion control matters?
A. I believe I did.
Q. Do you recall that the GAO

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specifically recommended that the DEA revise the regulation -- revise the regulation pertaining to suspicious orders to provide greater clarity?
A. I don't really want to speak on that document. Do you have a copy?
Q. I do. But right now I want to know whether you remember it.
A. Well, no. Well, I don't remember that -- I remember the document. I don't remember that specific statement. And I don't know that it addressed back to 2015 unless we've moved from the previous question, so...
Q. Do you recall that the GAO had three specific recommendations that it issued to the DEA on the topic of improving communication with registrants and industry? Do you recall that?
A. I remember there were recommendations.
Q. Do you remember that there were three of them, only three of them?
A. No, sir.
Q. And do you remember that one of

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the three was to revise the regulation pertaining to suspicious order reporting in order to provide greater clarity?
A. I'd like to see the document. I don't have independent recollection of that statement.
Q. Okay. Let's see if I can find it.
Before we look at it, if indeed the GAO -- I think GAO stands for Government Accounting Organization; is that right? Government --
A. Accountability.
Q. -- Accountability --
A. Office.
Q. -- Office. I should know these things.
If that was the GAO's -- and what is the Government Accountability Office's job? Do you know?
A. Kind of exactly what it says. They're tasked with -- and I don't know what initiates them to come in and do an accountability study, whether it's a directive from the legislature or how they go

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about doing an accountability, but they come in to organizations within the government and evaluate topics at the -- I'm just not sure at the request of who. Maybe the document would say that.
Q. So in this case they did an accountability study of the DEA, correct?
A. I do remember that they did a study, and I think it was on the -- I don't think it was specific to this particular topic. I think it was of the organization.
My recollection -- well, I don't want to speak about my recollection if we could just use the document.
Q. Okay. Let's just take a look at it.
(Whereupon, Deposition Exhibit Rafalski-6, 5/10/19 GAO Publication on Prescription Drugs [No Bates], was marked for identification.)
BY MR. NICHOLAS:
Q. What I'm going to show you is something from the GAO's website, actually, and you can just -- we can identify it. Just the heading of it is Prescription Drugs:

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More DEA information about registrants' controlled substances roles could improve their understanding and help ensure access.
That's the heading of the document.
A. Uh-huh.
MR. FULLER: For the record, it's not the actual GAO report, correct?
MR. NICHOLAS: No, it's a website summarizing aspects of the report.
MR. FULLER: Got it. Thanks.
BY MR. NICHOLAS:
Q. And this is dated May of 2019, so I don't want to misrepresent that this is a document that came out in 2015, although that document is -- that date is on here, but this I believe was run off on May of 2019.
And if you go to the second page, and the second recommendation, the recommendation reads as follows: In order to strengthen DEA's communication with and guidance for registrants and associations representing registrants as well as

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supporting the Office of Diversion Control's mission of preventing diversion while ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical needs, the deputy assistant administrator for the Office of Diversion Control should solicit input from distributors or associations representing distributors and develop additional guidance for distributors regarding their roles and responsibilities for suspicious order monitoring and reporting.
Do you see that?
A. Yes, I do.
Q. Okay. And the comment that the DEA provided in response to that recommendation was as follows: In February 2018, DEA reported that the agency had reviewed and revised the current regulation regarding suspicious orders and that the revised draft rule was undergoing internal DEA review. DEA reported in August of 2018 that they anticipated sending the draft rule to the Department of Justice's Office of Legal Policies by the end of the

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first quarter of fiscal year 2019.
We plan to continue to monitor the agency's efforts in this area and this recommendation remains open.
So you see that?
A. I see that.
Q. So it's clear from this that the -- that the DEA was, in fact, for some period of time working on revising the regulation pertaining to suspicious orders, correct?
A. Well, when you read this, I mean, that's the assumption you would make. I'm not aware of any changes or how they change it. And it doesn't influence my opinion on what the responsibilities were in regards to my report or what the requirements of the regulation were all the way back till it came into place in 1971.
Q. Well, we have a -- we just looked at a letter from the National Association of Chain Drug Stores in which that organization, on behalf of various chain drug stores, expressed a desire for greater clarity in the regulation.

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You saw that, right?
A. Yes, sir.
Q. Okay. And now we have the GAO acknowledging -- I'm sorry, we have the DEA acknowledging in response to a recommendation from the GAO that they are, in fact -- that they were, in fact, working on a revision to the regulation, correct?
A. That's what that says, yes, sir.
Q. Okay. And do you know whatever became of that revised regulation, proposed revised regulation?
A. I don't have any direct knowledge or recollection or anyone has ever told me what the status was of that regulation, but I'd just like to reiterate, whether or not the regulation has changed or going to be changed, it doesn't change my opinion because -- because of that, of what was required of these companies during the timeline of my report.
I would say that I think the DEA was providing a lot of communication to the industry, and I -- I don't know that they

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provided it to the NACDS. I know it seemed a little unusual that they were having individual meetings with registrants, doing distributor briefings. They do conferences, industry conferences.
And it's been my knowledge and my experience that any registrant that requests a meeting with the DEA at headquarters, they're always provided. Maybe not as timely as they'd like, but I'm not aware of the DEA just refused to ever meet with anyone.
Now, I'm a little concerned because I don't really in my experience deal with organizations that aren't registrants. I'm a little cautious about -- or in the DEA realm of dealing with -- I don't know if this is a lobbying group or if it's just a trade association, that they would make comments to trade associations when I think they would rather directly deal with registrants, so...
Q. Is it significant to you in any way that the DEA, for a period of several years, worked on revising the regulation pertaining to suspicious order reporting and

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monitoring? Is it significant to you in any way?
A. In a broad answer to that question, I think the DEA should always be looking at and evaluating regulations and how they affect the industry, not just a suspicious order system.
In regards to how they were going to change it or what new statement they were going to make, I have no awareness of that, but I would hope that the DEA or any governmental organization wouldn't just have regulations that they just allow to remain static if they, you know -- I would hope they're always under review.
Q. Well, this regulation had remained the same in language since 1974?
A. '1.
Q. '1, '71?
A. 1971.
Q. So not one word of it had been changed from 1971 until the present -- until the present, correct?
A. Well, it's my opinion there's a reason for that, and --

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Q. So I'm just asking you whether it's correct that it hasn't changed since 1971.
A. Well --
Q. Has it changed since 1971?
A. It's exactly the same as 1971. And I'd like to just reiterate --
Q. You can, but wait a minute. Hold on.
And do you believe that it is appropriate to update that language?
MR. FULLER: So object to the form of the last question prior to this and cutting off the witness. He has a right to finish his answers, and let the record reflect that the answers are incomplete as taken.
MR. NICHOLAS: Understood.
THE WITNESS: Could you state your -- this question one more time, please? I'm sorry.
BY MR. NICHOLAS:
Q. Do you believe that it is appropriate to update the language of the regulation?

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A. I think I stated that in my previous answer. Of this regulation or any regulation?
Q. This one.
A. No, I think the regulation is fine exactly as it stands.
Q. And would you continue to say that if you understood that both industry and people within the DEA have expressed confusion about the meaning of the language?
A. Well, I'm only speaking from my experience and conducting my investigations in dealing with registrants, and I guess sometimes when I look at that regulation and if I thought I had the role of being a distributor or a manufacturer, I would want it to be as nonrestrictive and broad as possible to design the best system based on the type of company that I had and the scope of my business model and who my customers were.
So I think changing the regulation is a -- I hope that if it is changed, that it takes that into consideration because I don't really think

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there's a one-size-fits-all.
I think there's some expectations of the regulation, but I hope that my experience, again -- I keep harkening back -- is that industry has always been asking for just what is a system and design it. And that's not possible because there's so many different types of businesses and types of customers. It's got to be tailored to the company's business.
Q. And the customers change, the customers' businesses change, the hospitals and the doctors change. All that stuff is constantly changing, correct?
A. That's exactly my point.
Q. Yeah.
A. It's never a static industry. The types of diversion change, the types of drugs change, and to make a regulation that would be very restrictive would probably cause diversion.
MR. NICHOLAS: We'll just do one more segment here and then we can break for lunch.
MR. FULLER: Sure.

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BY MR. NICHOLAS:
Q. Now, you talked a few minutes ago about what you referred to as the DEA distributor initiative briefings?
A. Yes, sir.
Q. Okay. And you also talk about those in your report; is that right?
A. Yes, sir.
Q. Okay. And in your report, if I have this correct, you refer to DEA distributor initiative briefings in 2005 and 2006 and in 2017; is that right?
I'm not sure that you refer to any others. I don't believe you do.
A. What -- what part specifically are you...
Q. You know, I don't have -- I don't have a page number for you in your report. How about if we do it from memory, and then if you want to look at your report, you can.
A. No, I'm not comfortable. I might get a detail wrong.
Q. All right.
A. So if you're talking about the

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actual briefings that occurred, they were specific to -- specific to some of the companies, and there was one that occurred in 2017.

There's -- in my report or in my personal knowledge, I know that they continued on long after 2005, and they went for some period. There was a couple years, two or three years, where they stopped and then resumed.

Q. Why did they stop?

A. I never was aware they did until working on this case, or actually, I don't know that I ever saw -- let me retract that.

I think it was in a deposition that I -- there may have been a discussion where they had stopped for a period of years, and I'm not sure why.

Q. Well, did you read about why? I mean, when you read about it, did you read any explanation as to why, in whatever you read?

What did you read?

A. I read that they had stopped

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doing it for a period of years and then resumed them, but I don't remember what the reason was stated.

Q. Do you remember who said that?

A. I don't want to guess, no, sir.

Q. Okay. And you don't remember any reason being given?

A. Well, I don't remember reading any reason being given. I don't -- I'm not sure whether there was a reason.

Q. Did you -- I believe you told us earlier that you only reviewed about 20 pages of Demetra Ashley's deposition.

Do you recall saying that this morning?

A. Yeah, I think I might have corrected it and said or a few more, but I don't recall reading it all the way to conclusion.

Q. Why not? Why didn't you read it all the way to -- what was -- why did you decide to stop reading that deposition after 20 or so pages?

A. Well, I think I said -- I didn't say the definitive amount. I think I

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corrected myself. I -- I don't want to say I didn't see much value in it. I just --

Q. After 20 pages?

A. No, I read it a lot longer than 20 pages.

Q. Wait. Did you read it a lot longer than 20 pages? Did you read 20 pages? Did you read a little longer? Do you not know?

A. I'm not exactly sure how long. I know I didn't read it to conclusion. I don't really have an explanation. I just was in the middle of finalizing or working on my report. I just didn't see -- I don't want to say a lot of value in it because everything has value, but I just -- I don't know why. I just didn't complete reading it.

Q. So you didn't see her discussion in the deposition about the fact that these distributor initiative briefings were stopped for a period of time and why?

A. I don't recall that in her -- that I read that in her deposition. If you were just asking me to give a recollection, I would think it was Mr. Prevoznik's, but I'm

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not sure.

Q. Well, do you recall what Mr. Prevoznik's explanation was, was that they were stopped for a period of time because of pending litigation?

Do you recall that?

A. I don't remember the litigation. I thought maybe it said investigations or some kind of pending matter, but I don't remember that it was litigation.

Q. Well, I'll represent to you that he actually said litigation.

A. Okay.

Q. Does that seem appropriate to you?

A. That they suspend them for litigation purposes?

Q. Yeah. Yeah.

MR. FULLER: Object to form.

A. I don't know what the litigation was, so I don't really have a comment on that.

BY MR. NICHOLAS:

Q. Well --

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A. I guess that's Mr. Prevoznik's issue to comment on.
I'm not sure, under my authorization from the DEA, if I even knew I could comment on that.
Q. In your report -- and you can turn to the pages if you want. Starting on page 40, you make reference to five different methodologies that address the issue of the number of suspicious orders that were and weren't reported in the Track 1 jurisdictions, correct?
A. I think I report dosage amounts based on the methodologies.
Q. I'm sorry. I'm sorry. I apologize. Dosage amounts.
So we're talking about the number of -- however you want to describe it, the number of pills or the number of dosage amounts of pills that are going into these jurisdictions over a period of time; is that right?
A. Yes, based on that particular methodology.
Q. Okay. Well, you say that

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particular methodology. You used -- you referenced five methodologies, correct?
A. Yes, sir.
Q. Okay. Did you figure out those methodologies yourself, or did Mr. McCann do that?
A. No, those are mine based on --
Q. These five methodologies are yours?
A. Yes. Well, they are methodologies that are mirroring suspicious order systems that are utilized by one or more companies in my report.
Q. Okay. So did you -- you put these -- did you put these charts together yourself?
A. No, I did not.
Q. Who put the charts together?
A. I -- I'm sorry.
Well, this is based on McCann's -- Mr. McCann takes -- took my methodology, and these were the results of his application of my methodology to the ARCOS data.
Q. I see.

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So you -- you came up with these five methodologies?
A. Yes, sir.
Q. Okay. And tell me -- tell me why you chose these five methodologies. I think you started to do it, but just go ahead and explain it to me.
A. Well, because these are methodologies that were used by one or more companies in my report, during the time frame of my report. Each one of these were not invented by me, but they were actually used.
Q. Okay. Can you -- let's start with the first one. Methodology A is maximum monthly trailing six-month threshold.
Can you explain to me what you were trying to express here?
A. Well, this is the Masters case methodology.
Q. Okay.
A. Or I shouldn't say methodology. This is their suspicious order system. So it's a rolling six-month, and it looks for a current month that exceeds the highest previous amount in the six months.

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Q. Okay. And so when you refer to flagged orders, you've got -- you know, your top column, it's a grid.
A. Yep.
Q. And from left to right, across the top, first it's the name of the distributor. Then it says: Flagged orders of oxycodone (dosage units). Then it says: Flagged orders of hydrocodone (dosage units).
Let's just take AmerisourceBergen, since this is the first one.
A. Okay.
Q. Okay. Go down to orders of oxycodone (dosage units), and then it says the number, which is 50,578,040.
What's that a number of, dosage units?
A. Yes.
Q. Okay. And then what does the 86% of total dosage units mean? What is that -- 86.5% of what?
A. Of the amount that was distributed during the time period stated above into the CT1 jurisdiction.

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Q. Okay. And then moving across to the 24th -- to the flagged orders of hydrocodone dosage units, it's 24,412,050, which represents 92.7% of the total dosage units, correct?
A. Yes, sir.
Q. So are you saying -- well, what are you saying when you express this? I shouldn't say.
I mean, you're showing it. What does it mean?
A. So the methodologies applied to the distribution, once the suspicious order is identified, the criteria I used is if there was no due diligence to dispel the suspicious order or it wasn't reported, then every subsequent distribution would be a suspicious order.
Q. Let me -- I hate this expression, but I'm going to have to unpack that.
So the criteria you used -- you say once the suspicious order is identified?
A. By the company -- or by the methodology, I'm sorry.

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Q. I mean, that's my first source of confusion is, are these suspicious orders or are these what you are suggesting should have been suspicious orders, that you're basing this on?
A. Well, it's not suspicious --
MR. FULLER: Objection to form.
A. It's not suspicious orders. It's dosage amounts that resulted from suspicious orders. So the methodology -- my understanding of what Mr. McCann did -- and I don't want to speak for him.
BY MR. NICHOLAS:
Q. Okay.
A. -- is he looks at the distribution, the ARCOS data for the distribution for AmerisourceBergen drug company, he applies the methodology, and if there are no suspicious orders, it just runs along the distribution.
At some point, if there's a month that exceeds the greatest month in the previous six-month, that stops and it's a suspicious order. So at that point, if there was a due diligence to dispel that suspicious

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order, if I could find that in my investigation, then it would continue on.
If there was no due diligence and, as my report details, there wasn't during the early time periods -- during most of the time period there was no due diligence to dispel suspicious orders, so every subsequent order would become a suspicious order.
Q. On what basis are you saying that there was no due diligence done to -- with regard to flagged orders? What is your basis for saying that?
A. There were review of records submitted on discovery.
Q. Records for --
A. Now, let me -- can I correct this?
Q. Yeah.
A. I don't want to say none whatsoever. I believe that probably there may have been some individual instances of due diligence, but in a general statement, at a systematic level, there was insufficient due diligence. Or none.

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Q. And what is your basis for that statement?
A. Reviewing records.
Q. Reviewing records provided to you by the plaintiffs?
A. By the drug companies under discovery.
Q. You only had access to the records that the drug companies supplied in discovery to the extent they were sent to you by the plaintiffs' lawyers that were retaining you, correct?
MR. FULLER: Object to form.
A. I'm not sure how to answer that because I guess I hope I got all the records.
Now, I'm not indicating that I looked at every one, but I looked at enough to draw a conclusion or an opinion that there was insufficient due diligence.
BY MR. NICHOLAS:
Q. Well, if you weren't sent records that are -- that exist, how do you know how many of the -- how many -- how do you know whether you looked at a few, some, most or all of the records? How do you know?

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A. I think that's kind of a hypothetical question.
Q. No, it's not hypothetical. You told me that -- you told me that you obtained records from plaintiffs' counsel, correct?
A. And it's my belief that I had access to all the records. Now, there's no way that I would know if that occurred or not. That's -- I'm hopeful, as their expert opinion, that I had access to all of the records.
I can't affirmatively say that they gave me every record. I -- that's why it's kind of a hypothetical.
Q. Well, right now it is a hypothetical because we really have no idea what records you were provided, what records you were provided and what you weren't because I think you told us that you didn't write down all the records that were provided to you.
A. Well, I would say that in regards to this matter, I reviewed sufficient due diligence records to draw -- to make my opinion.

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Q. Now, sticking with that for a minute, just because you did not review due diligence records from 2010, 2011, 2012 -- let's assume you didn't see due diligence records or as many as you would have liked. That doesn't mean that the due diligence wasn't done, does it?
A. Well, as far as the DEA is concerned, if there's no documentation or record of it, a due diligence file, my opinion would be based on that that doesn't exist.
Q. Well, we've already discussed the fact that there was no requirement in the regulations as to the retention of due diligence records --
MR. FULLER: Object to form.
BY MR. NICHOLAS:
Q. -- for any period of time, right?
MR. FULLER: Object to form.
That's not the witness's testimony.
A. So I don't think that's exactly what my statement was. I think my statement was is that it wasn't contained as a required

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record in the recordkeeping section of the CFR.
BY MR. NICHOLAS:
Q. Yeah.
A. But it was of my opinion that it's covered under the maintenance of effective controls, and it would be my opinion as -- with my experience and my training and my knowledge, is that it should be kept forever. It's a historical record, and it should be kept by the registrant much greater than two years.
Q. Now, you keep saying that the requirement to maintain records is contained in the section pertaining to maintenance of effective controls, but just so the record is clear, there's nothing in the section on the maintenance of effective controls that makes any reference to records, correct?
A. Well, I --
MR. FULLER: Form.
A. I think within the statements, that's what that statement means.
BY MR. NICHOLAS:
Q. Means. But I'm asking whether

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there's any actual written reference to records or the retention of records in that section?
A. Well, so in the maintenance of effective controls?
Q. Yeah.
A. It doesn't specifically say that, if that's what you're...
Q. Okay. Okay. Now -- so just -- we'll break for lunch, but just so I understand, the methodologies that -- the five methodologies described here were selected -- were identified or selected by you. Is that -- based on what you saw the various companies had done over the years; is that correct?
A. Yes, sir.
Q. And you provided just those methodologies, the concepts, to Mr. McCann and he plugged in the numbers; is that correct?
A. Yes, but just as a clarification, I personally didn't discuss that with Mr. McCann. I discussed it with counsel and then counsel relayed that to

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Mr. McCann. And then it didn't come -- I didn't have -- I've never had a personal discussion with Mr. McCann about this. It was relayed through attorneys and back.

Q. Okay. Now, there are five methodologies here. Which one are you endorsing?

A. None.

Q. You don't endorse any of them?

A. No, sir.

Q. Okay.

A. I used these methodologies because they were used by the industry. So I didn't want to impose a methodology that wasn't, you know, recognized or utilized by one or multiple distributors.

MR. NICHOLAS: Okay. Okay. Let's take a break.

THE VIDEOGRAPHER: Going off the record at 12:46 p.m.

(Recess taken, 12:46 p.m. to 1:30 p.m.)

THE VIDEOGRAPHER: We're back on the record at 1:30 p.m.

MR. FULLER: Counsel, I think

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Mr. Rafalski had something he wanted to clarify related to his last -- or your last question.

THE WITNESS: I don't know if it was the last or one of the last. I apologize, I think I was more focused on going to the bathroom than the question.

But you asked if I endorsed a methodology.

MR. NICHOLAS: Uh-huh.

THE WITNESS: I guess I understood -- or I believed that question was asking if I endorsed a methodology as a suspicious order system or whether I endorsed it as one of my methodologies.

So I'm -- I answered it because I thought you thought I would endorse it as a suspicious order system, so I'm not sure how you asked that question. So I --

BY MR. NICHOLAS:

Q. Okay. No, I appreciate that. I'm glad you did the clarification.

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So you don't -- so --

A. I didn't want to say that I didn't endorse my own methodology.

Q. Okay. So of these five, which methodology, if any, do you favor or endorse for purposes of the analysis you're doing?

A. That would be the Masters.

Q. Okay.

MR. FULLER: Which is the first one, right?

THE WITNESS: And that's -- yes, that's methodology one.

A. And essentially because it has been reviewed and an order issued -- or an opinion issued by the D.C. court.

BY MR. NICHOLAS:

Q. Now, just work with me here, because I want to make sure I'm understanding what you're saying and also what you're not saying, okay?

Let's just look at the column for -- I'm on page 41.

A. Okay.

Q. The column for, I don't know, flagged orders of oxycodone dosage units, and

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you go right down each company, all right. You've got one, two, three, four, five companies, and in the case of each one, you've got a parenthetical that says that somewhere between -- that identifies somewhere between 86.5% and 95.3% of total dosage units, okay?

A. Yes, sir.

Q. All right. And that means what? Is that the number of dosage units that in your opinion should not have been shipped?

A. Well, in my report, if we -- I actually make a statement in regards to that on page 46.

Q. Okay.

A. So it starts after the footnote 151: However, it is my opinion to a reasonable degree of professional certainty that applying the tests set forth in the Masters Inc. and Drug Enforcement Administration provides a reasonable estimate and initial trigger on a first step to identifying orders of unusual size.

Q. So are you saying that --

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A. Well --
Q. -- this is the number of --
MR. FULLER: Well, go ahead and finish your answer.
MR. NICHOLAS: Okay. I thought you were done. Sorry.
A. So -- and I can read the rest of the paragraph.
BY MR. NICHOLAS:
Q. Don't read. I'd rather you just tell me just in words, in your words, what -- you know, what is it you're trying to convey here?
Are you trying -- are you trying to say, or are you saying that in your opinion, 86.5% of the total dosage units for Ameri- -- you know, under the AmerisourceBergen drug thing, are dosage units that should have been reported as suspicious orders?
A. I'm saying based on my experience and my opinion, based on some documents that when a suspicious order occurs as a result of the methodology and there's no action taken, no due diligence action taken

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to dispel that suspicious order, that all the -- all the orders from that point forward, I'm considering them to be, you know, the result of suspicious orders.
Now, that --
Q. Okay. All right. So my question is -- all right. So let me try this.
Are you suggesting in your report that more orders should have been reported as suspicious?
A. Well, I don't think it suggests that. I'll restate it again.
So when the system triggers a suspicious order, it doesn't reset to the next order to be a suspicious order. So how I interpret the regulations and how my training is and how the Masters ruling and some of the documents I've read in regards from McKesson and Cardinal and Prevoznik's deposition testimony, is that once a suspicious order is identified by registrant, it should be stopped and there should be a due diligence to dispel whether or not that suspicious order is in fact suspicious.

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If the registrant takes no action and just continues to ship subsequent orders in that order, then they're all suspicious orders.
Now, my last paragraph kind of sums up that this is how I applied this, and, you know, it's in regards to how the court would or would not accept it and there would be other methodologies. So that's how I interpret it.
Q. You know, on this subject I think -- well, are you able to tell us -- are you able to -- well, let's see.
Let's say an order is identified by a distributor as suspicious, okay?
A. Yes, sir.
Q. And it's reported to the DEA as suspicious.
A. Yes, sir.
Q. Okay. You agree that that doesn't necessarily mean that that order -- that the pills associated with that order are going to be diverted, right?
A. No, I think that's exactly what

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it means.
Q. You think every time that an order is reported as suspicious that those pills turn out to be diverted?
A. I don't know that I could draw that conclusion, but I --
Q. That's the conclusion I'm asking you about.
A. Well, I wouldn't draw that conclusion. The only conclusion I would draw is that if a registrant is adhering to the law and the regulations and has a suspicious order system in place and their system identifies that, I would hope that they believe that they're reporting to the DEA what they believe to be a suspicious order.
Q. I'm asking you a completely different question, okay?
My question to you is: When an order was reported as suspicious -- strike that. Strike that, because I -- I asked a confusing question.
I think what you're saying is that there are -- but tell me if I'm wrong -- is that more orders should have been reported

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as suspicious than were reported; is that right?
A. No.
Q. Okay. So you think that the appropriate number of orders --
A. I --
Q. -- into Track 1 and Track 2 jurisdictions that were reported as suspicious was indeed appropriate, that the right number was reported?
A. This methodology doesn't look at it that way because there was no due diligence so --
Q. Hold on. Let me stop you there.
MR. FULLER: Well, object --
MR. NICHOLAS: Go ahead. No, I'm sorry. You're right. You're right. Go ahead.
A. Because there was no due diligence. So the methodology is not applied to identify future orders that are suspicious, because when you don't dispel the suspicion or the potential that it's going to be diverted and you can clear it to say that

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it's not going to be diverted, then every subsequent order, in my -- in the way I've applied this, would be a suspicious order based on the policies and the guidance and my experience with the DEA.
BY MR. NICHOLAS:
Q. So your entire analysis here rests on the premise that no due diligence was done on the orders that you're reporting on here; is that right?
MR. FULLER: Object to form, misstates his prior testimony.
A. No -- either no or insufficient due diligence.
BY MR. NICHOLAS:
Q. Okay. So there was either no due diligence or insufficient due diligence on, in the case of AmerisourceBergen, 50,578,040 dosage units. That's what you're suggesting?
A. Just so that I'm clear so we understand each other, that represents total dosage units and it's not orders. But, so at some point, if there was an effective due diligence, then I believe the methodology

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would start monitoring it again until the next instance where there would be a suspicious order, and then that would require due diligence whether or not to clear that.
So it's -- you know, the critical thing I think that we -- that, you know, that we are having trouble communicating --
Q. We're definitely not communicating right now and I'm sure I'm not understanding this.
A. -- back and forth is the concept that when you don't do due diligence, that that makes every subsequent order a suspicious order.
Now --
Q. That's what you're saying?
A. Yes, if there is insufficient or there's incomplete or there's no due diligence.
Now, that's a methodology that's, I think, up to the court whether or not to accept, but that's -- so it's just as long as you understand clearly on how I had this methodology applied.

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Q. So again, your methodology rests on your --
A. Opinion.
Q. -- conclusion or opinion that either no due diligence was applied or insufficient due diligence was applied -- you know, was utilized by any of these companies, and that results in these large numbers of dosage units and these percentages; is that right?
A. Yes, sir. My -- I'd like to add to that as my final -- the final in the -- on again, on 46, and this will maybe be a clarification of what I said earlier, the last sentence of the first paragraph: I say this understanding that the litigation will be advanced by selecting a methodology qualifying a volume of pills that entered the CT1 jurisdictions unlawfully and providing this data to an economist to measure harm caused by this volume.
Q. Yeah. You say in the -- the first sentence of that paragraph says: I've been asked to identify the number of opioid pills that entered Cuyahoga and Summit

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Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their federal, statutory and regulatory requirements.

What failure are you referring to? The failure to do due diligence?

A. That would be the main obligation under the law, the maintenance of effective controls would be to do due diligence, or I guess as you have asked me earlier, if due diligence occurred and there's no documentation, there's no way for me to know that it ever existed, nor is it for the registrant to know if an order came in two days later. There's no historical record of it.

Q. So part of the assumption here -- because you're going back in this methodology to 1996, right?

A. Yes, sir.

Q. And so what you're saying is that if you don't see documentation of due diligence from 1996 or 1997, say, then you're concluding for purposes of this report that the due diligence didn't occur?

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A. That's not what I respond -- how I answered the question just a couple of questions ago.

So there could have been at some point for each of these companies where they designed or developed a system where they met the regulatory and the legal requirements. They had due diligence. They had an effective system, and they began to identify suspicious orders, and they -- they did a -- more than a cursory approval and they did due diligence. So that would stop the count.

And then the methodology would be applied again, and every one that was identified, if there was effective due diligence, it wouldn't be counted as a distribution to the CT1.

Q. Did you stop the count at any point in this analysis?

A. No, sir.

Q. And that's because you assumed that there was no due diligence done at any point from 1996 to your end date here --

MR. FULLER: Object --

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BY MR. NICHOLAS:

Q. -- at least for the purposes of your numbers?

MR. FULLER: Object to form.

A. It's not an assumption. It's based on my review of records and depositions and documents that I couldn't find a time period where I believed there was sufficient due diligence -- well, there was actually a complete failure.

There was the failure to stop suspicious orders, there was ineffective suspicious order systems, but in regards to what caused these large numbers, it was the failure to have the maintenance of effective controls to prevent diversion, which is the act of the due diligence, the reviewing those orders to approve them as was detailed in the Masters opinion.

BY MR. NICHOLAS:

Q. Okay. Now, see if we can agree on one thing here, which is this: There could be an order of unusual size or frequency or pattern that is shipped. Whether it should have been or shouldn't have

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been, we can put aside for another day. Okay? Let's just say that there's an order of unusual size, frequency, pattern, that, in fact, was shipped and it -- you can even say -- and let's say it should have been reported as a suspicious order, but it shipped. All right?

Do you agree that even though that order was shipped and even though you say it shouldn't have been shipped, it doesn't necessarily mean that the pills that underlie that order are going to be diverted. You don't know.

MR. FULLER: Object to form.

BY MR. NICHOLAS:

Q. Correct?

A. So I'll answer that question by saying that if it's identified as suspicious order by unusual size or unusual frequency or deviating form -- you know, substantial deviation from a pattern, so to me that puts it as a probable, greater than 51% that it's going to be diverted because it's been identified.

So I can't draw the conclusion

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that I don't know that it's going to be diverted. I probably can't draw a definitive statement that it is, but I'm going to say that it's more probable because the system identified it.

Q. So you got it at 51% above, it's going to be diverted; is that what you're telling me?

A. Well, that's the definition of probable. If it's an effective suspicious order system, I believe the percents would rise much higher than that, but I guess that depends on the effectiveness of the suspicious order system.

Q. Where are you getting that percent from? Where are you getting that from, just your own --

A. What?

Q. The 51, the probable, where are you getting that it's probable?

A. That's my belief of what probable means.

Q. Okay. Other than your belief, is it written down anywhere? Is there any research on that? Is there any data on that?

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Is this just -- just your belief?

A. Not that I can cite.

Q. Okay.

MR. FULLER: Vegas odds.

MR. NICHOLAS: Okay.

BY MR. NICHOLAS:

Q. Did you look at any individual orders from any pharmacies in the Cuyahoga or Summit Counties?

A. I looked at some DEA 222 forms, but I believe my recollection, it was out of maybe the Boston area, so I would say no.

Q. Okay.

A. No original records. I reviewed no original records.

Q. You reviewed data that was in the aggregate, right, totals? Correct?

A. No. I reviewed -- so just so we're clear on, you know, what we're talking about, so there's no confusion.

Q. Uh-huh.

A. So to me, in the DEA world, an original record is the actual DEA order form, the invoice or a CSOS electronic order form. So that's what I would consider an original

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record. Also provided to me, there's the ARCOS data, which is not an original record, and there were some electronic databases that appeared to me to be an electronic spreadsheet or an electronic format of orders that distributors or registrants had submitted as part of the discovery. But none of those would be what I would consider an original record.

Q. Can you identify a particular order from a particular pharmacy that you believe should have been reported as suspicious?

A. Well, in my assignment to create this and do the investigation to come to this opinion, there wasn't a requirement for me to actually find specific orders that were suspicious.

First of all, it would require the use of the suspicious order system of the registrant, like what would be the criteria. The -- and the thing I found in doing my opinion is that probably the most critical part of setting up a suspicious order system is the due diligence or sometimes in the

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industry they call it the onboarding, and that's to establish what the criteria is. I said earlier what the usual is.

And I found it difficult because I didn't really find an adequate effort to set up what actually would be a usual or what would be an expected order. So for me to go in and try to make that kind of analysis wouldn't be possible.

Q. So sitting here today, you can't identify a particular order from a particular pharmacy that should have been reported as suspicious that wasn't; is that correct?

MR. FULLER: Form.

A. I don't know because I didn't task myself to do that.

BY MR. NICHOLAS:

Q. Sitting here today, can you do it? I know you didn't -- I know it wasn't part of your job description here. That's all I want to know is can you do it today? Is it part of your report?

A. Well, actually, let me retract. I think I did that and I think it's on

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page 59 of my report. I think I used a methodology. I believe it was the Cardinal methodology, cage pickers, and I applied their methodology to the orders and I believe I came up with a total. Yes, it's on page 59. So Cardinal had in place an excessive orders system. At the beginning it says: Cardinal Health Systems early 1990s to 2008 was also designed to identify individual orders that appear to be excessive, on a daily basis, and notify the DEA if possible before the order is shipped.

Excessive orders are defined by the following dosage limits. And these limits, among many others, were posted in the cage -- or the vault in the Cardinal facility.

Q. What page are you on? I'm sorry?

A. 59.

Q. Yeah, okay. All right. I'm with you.

A. So I applied these amounts, and I -- well, I requested Mr. McCann to apply these amounts into the distribution records

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for Cardinal, and the result of using these amounts for Cuyahoga County was 1,000 -- 166,869 orders of oxycodone and the corresponding dosage amounts were 88,238,715. Those numbers aren't dependent on due diligence. Those would be the amount of orders, if Cardinal would have used that system and applied it to their distribution, those were the number of orders that they would have reported to the DEA, and that's the corresponding dosage units. And they reported none during that time period, using this system.

Q. Have you identified a particular order in the answer you just gave me?

A. Yes, 166,869. I didn't ask Mr. McCann to give me the list of each of the orders, but each one of those would be a specific order that should have been reported based on the system the registrant had in place.

MR. FULLER: Counsel, just for my clarification. You're just wanting him to pick out a specific date, a

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specific order out of all those that have been identified?

BY MR. NICHOLAS:

Q. I want to understand whether your analysis involved review of specific particular orders on particular days sent to particular -- sent by particular pharmacies to distributors. I think the answer to that is, no, not that -- it's not that controversial a question. I'm really just trying to get a simple yes-or-no answer.

A. Well --

Q. Did you look at individual orders that were sent to distributors, individual ones?

MR. FULLER: Object to form. Pharmacies don't send orders to distributors.

MR. NICHOLAS: Okay.

MR. FULLER: Well, I mean y'all chuckle. The question says for the record --

A. I didn't look on an individual basis --

MR. FULLER: Hold on. The

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question says, for the record, sent by particular pharmacies to distributors. That's the question you asked. Pharmacies don't send --

MR. NICHOLAS: What are you yelling at me for? I don't --

(Simultaneous discussion interrupted by the reporter.)

MR. NICHOLAS: Go ahead.

MR. FULLER: I'm sorry, I'm just trying to make sure the record is clear.

MR. NICHOLAS: So you were starting to answer.

THE WITNESS: Sorry. Could you ask the question again.

MR. NICHOLAS: Well, your lawyer managed to interrupt, so I'll have to do it again. Let's see.

BY MR. NICHOLAS:

Q. I want to understand whether your analysis involved review of specific particular orders on particular days, sent to particular -- sent by particular pharmacies to distributors.

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A. My analysis to form this opinion wasn't specific to looking at each order by order.
MR. FULLER: Object to form.
BY MR. NICHOLAS:
Q. For how long does the DEA retain suspicious order reports?
A. Just for clarification of your question, you mean the ones that are submitted to the DEA by registrant?
Q. Yes.
MR. FULLER: Object to form, and I'm going to instruct you not to answer if it is based on information you gained while being an agent and not otherwise known publicly.
THE WITNESS: I guess on the advice of counsel, I won't answer.
BY MR. NICHOLAS:
Q. In your review of all of the records in this case that you did review -- and I understand you didn't review all of them, but in your review of everything that you saw, can you tell me based on that for how long the DEA retains suspicious order

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reports?
A. No, I cannot answer that question.
Q. In your review of all these records in the case, did you see any instances of the DEA retaining any suspicious order reports?
A. Yes. And my answer would be in regards to my experience and knowledge, that they're submitted electronically to DEA headquarters and that there's, I'm sure, a retention because they're available for review.
Q. Are suspicious order reports kept in a database by the DEA?
MR. FULLER: Objection. Same instruction.
THE WITNESS: On advice of counsel, I'm not going to answer that question.
BY MR. NICHOLAS:
Q. So you're following your counsel's instruction not to answer the question of whether the DEA keeps suspicious order reports on a database?

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A. Well, I guess I'm going to not answer, not based -- well, based on his instruction, but it's because whether it's a fact that's known by -- discoverable by just the general public, and I -- I don't know, so that kind of makes me not want to answer that question because I don't know if a person could just do some query from the general public and obtain that answer.
Q. Well, I can tell you that this deposition is designated as a confidential process to which the public does not have access and will not have access.
So with that assurance, can you answer the question now as to whether -- the simple question of whether the DEA keeps suspicious order reports on a database?
MR. FULLER: No, Counsel, hold on one second. The Touhy request has no bearing on whether this is kept confidential or not. Touhy authorization says he can't testify to anything that is not publicly known and that he gained information during his employment. Touhy authorization

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allows him to testify based on the facts reviewed and provided in this case. So I'm still going to give him the same instruction.
I'll be honest with you, I don't know if it's public knowledge or not, whether it's in a database or not. It may be.
MR. NICHOLAS: Okay.
BY MR. NICHOLAS:
Q. Do you agree with the statement made by Mr. Rannazzisi in his deposition that 99% of doctors prescribe opioids for legitimate medical purposes?
A. I don't really have an opinion or I really don't agree or disagree. I don't have sufficient knowledge or experience or reviewed any studies to be able to make a comment on that.
Q. And do you agree with the statement made by Mr. Patterson of the DEA, formerly of the DEA, testifying in front of Congress that 99.9% of doctors are trying to do the right thing?
A. My answer --

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MR. FULLER: Form.
Go ahead.
A. My answer would be the same. I -- I don't know the pure math of that question, but with over 1 million doctors, 99.9%, I'm not sure --
BY MR. NICHOLAS:
Q. Do you think the vast majority of doctors are trying to do the right thing?
MR. FULLER: Form, scope.
MR. NICHOLAS: You can answer.
A. I would agree with that, that I have no experience or knowledge that says, you know, anything otherwise than the vast majority. I guess we could maybe dispute about what vast majority is, but...
BY MR. NICHOLAS:
Q. When do you believe the opioid crisis began?
A. I would probably say the onset would be the Internet pharmacy activity, the illicit Internet pharmacy activity, I think 1999, around in that time period.
Q. Okay. When did you first become aware that there was an opioid crisis?

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Around that time?
A. No. Probably when I started my employment with the DEA in the academy.
Q. 2004?
A. Yes, sir.
Q. Is there a point at which you believe the opioid crisis became common knowledge?
A. Yes.
Q. When is that?
A. Well, could I get a clarification of what you believe is common knowledge? Because what's common knowledge to me is -- would you -- would your definition of that be just if you were to stop somebody and say what is an opioid?
Q. How about known to government entities, cities, towns, counties, states.
MR. FULLER: Form.
A. Well, I think it's -- I think it probably coincided with when the Internet pharmacy illicit conduct got to -- identified. There was a study that was being done and it was published and showed the conduct of these Internet pharmacies and

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distributions not pursuant to a prescription.
I think when that report was published, I think, at least in regards to -- that's my belief, that that's when it pretty much disclosed the scope of that activity.
BY MR. NICHOLAS:
Q. When was that study published, roughly?
A. 2004-2005.
Q. Okay.
A. Now, just so I can clarify my question, I think the DEA knew about it prior to that.
Q. Yeah.
A. So just the clarification was it would be just like when it really came out and people should have a better awareness of it, that would make -- okay?
Q. Okay. Yeah, I understand.
Now, each year the DEA sets a quota as to the number of controlled substances that are to be made available nationwide; is that correct?
A. Yes, sir.
Q. Okay.

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A. By law, I believe, and regulation.
Q. And over time, during the -- during the past years, there was a period when the number of opioid pills that were reaching various communities in the country was increasing, correct?
A. Yes, sir.
Q. Okay. In setting quotas each year, did the DEA overestimate the medical needs of the United States?
A. I don't really have sufficient knowledge because I didn't work in the quota section; it was done entirely in the headquarters section. I really don't -- can't give an opinion on that particular question.
I could maybe clarify that a little bit.
Q. Yes, please.
A. Just my experience and knowledge of just hearing about it and not being directly related, that those -- those quota amounts were approved based on information that the DEA received from

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manufacturers and distributors, and that was some of the things they used to guide them in setting the quota for the -- which is the medical and scientific needs of the country.

But other than that, I don't know how they evaluated that information.

Q. Well, does the DEA shoulder any responsibility for setting the quotas? I mean, does it have its own input, do its own analysis, do its own work?

MR. FULLER: Object to form, outside scope. And if it relates to anything you gained knowledge on while you were there that's not public knowledge, your Touhy authorization does not allow you to testify to it.

A. So -- I don't know, so my answer -- I can't say I won't answer, because I don't have any direct knowledge of that.

BY MR. NICHOLAS:

Q. Based on your personal experience and years with the DEA, do you believe that doctors went through a period of time when they were overprescribing opioids?

A. So could you clarify what you

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would consider to be overprescribing? Because there's a couple of different ways I think I could interpret that.

Q. Did doctors prescribe too many opioid -- well, strike that. I'll try it again.

A. Let me --

Q. Was there a period of time when -- or do you believe doctors prescribed more opioid pills than were medically necessary for their patients?

MR. FULLER: Object to form. He's not a medical doctor.

A. Well, my investigation into some of them that I detailed as at least bulleted in my report, would say that I would ask -- answer that affirmatively because I have some experience with doctors who did issue illicit or diverted prescriptions.

So, you know, just in a general answer would be yes. Now, I'm not going to qualify that with how many or what, but that's one of the essences of how diversion occurs.

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BY MR. NICHOLAS:

Q. Are you able to tell -- well, you wrote on your report on page 46, and we read this already, that you had been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully, and then you went on to say it's an impossible task, right? Page 46, first full paragraph.

A. Yes.

Q. Okay. Are you able to tell us the correct number of pills that should have been shipped into Cuyahoga and Summit Counties lawfully?

A. No, sir, I cannot provide that information -- or did I calculate that information or --

Q. Do you have any sense of it at all?

A. Well, I'm supportive of my opinion, and that's the failures by the registrants during the time period was a significant contribution to diversion and the amount of pills. But to put a calculated number, I can't do that. My methodology has

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come to some conclusions based on, you know, the due diligence factors.

Q. And in some regards, you'd almost have to be a doctor to know an answer to a question like that, right?

MR. FULLER: Form.

A. Well, I think that would be one aspect, to be a doctor. But then, you know, there's a lot of other factors that also would be taken into consideration.

BY MR. NICHOLAS:

Q. But, I mean, you don't feel qualified to look at a prescription for a patient and know whether that prescription is appropriate or not, correct?

A. Well --

MR. FULLER: Same objection.

A. I don't want to be argumentative, but in my experience of doing some cases, there have been instances where I could look at a prescription, knowing how it was written or the procedure that it was used, and I could say that that was not a legitimate prescription.

One example would be in one of

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the cases I worked, patients would meet doctors -- not patients. People would meet a doctor in a parking lot, pay a hundred dollars and get a prescription. So I don't know that I would have to be a doctor to be able to say that wasn't a legitimate prescription.

BY MR. NICHOLAS:

Q. Fair enough. Sounds like you're a little bit of a doctor, a little bit of a lawyer and a little bit of a witness.

A. I just think that that doesn't take either -- any of those quantifications to say that there's something wrong with that prescription.

Q. Okay. Just a little more, and then I'll be done.

Now, you attended DEA basic diversion investigator school in 2004; is that right?

A. Yes, sir.

Q. Was that training at Quantico?

A. Yes, sir, it was -- I don't want to say custodial training. It was a -- you actually stayed at the facility, 12-week

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training.

Q. As part of your training, did you go to AmerisourceBergen's Richmond distribution center?

A. No, sir, I don't believe so.

Q. Okay. Are you aware of other diversion investigator trainees who did so?

A. No, I'm not.

Q. Were you aware that AmerisourceBergen in 2004 and 2005 worked with the DEA to train DEA diversion investigators?

A. I was not aware of that.

Q. Were you provided any documents that would have shown you that?

A. I'm sure I was -- I think I was provided access to all documents, but I don't recall reviewing those particular documents.

Q. Okay. So to your knowledge, the plaintiffs' lawyers didn't send you documents pertaining to that; is that right?

A. I don't think I said that. I -- I think I --

Q. I'm not saying you said it. I'm asking you whether that's right, that to

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your knowledge, the plaintiffs' lawyers didn't send you those documents?

A. I can't answer affirmatively to that because I believe I had access to all the documents.

Q. Access to all the documents, but I'm talking about what was actually sent to you.

A. I think they were all -- in some form or another, electronically, or I think I had access to all the documents.

I guess just so I understand the question, no one physically gave it to me or said here is the document, but I don't think that -- I think somewhere in all of the production that they gave to me, that that document could exist.

Q. Okay. So --

A. I hope that makes sense.

Q. It makes sense, but I guess now I need to understand. So if you had access -- if you think -- you don't know, but you think maybe you had access to all the documents in the case?

MR. FULLER: Form.

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A. I believe I did. I don't think there were any documents withheld from me.

BY MR. NICHOLAS:

Q. But you don't know one way or the other, right?

A. Yeah, I think we discussed that before lunch.

Q. We went over this, yeah.

A. There's no way that anyone really knows --

Q. Right.

A. -- if -- that everything was turned over. My belief is that it was.

Q. Okay. And -- but in all those millions and millions of documents, you would need someone to point you in the direction of what to look at as opposed to what you don't need to look at, right?

A. That's correct.

Q. Okay.

A. And in my earlier testimony, I think I was clear that I didn't look individually at every document. There were people that assisted me in looking at documents and guiding me and directing me to

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certain documents, so it would be, I guess, maybe in a lifetime, physically -- I don't even know if it would have been a lifetime to look at 50 million documents, but there had to be some system to be able to look -- to help me form my opinion to look at relevant documents.

Q. Yeah. And that system was the plaintiffs' lawyers directing you toward the documents that they wanted you to look at?

MR. FULLER: Object to form.

BY MR. NICHOLAS:

Q. What other system was there?

A. Well, could you say the question one more time.

Q. The system by which you wound up reviewing some documents and not others was dependent on the plaintiffs' lawyers providing -- you know, directing you to the documents that they believed you should look at, right?

MR. FULLER: Object to form.

A. That's not a correct statement.

MR. FULLER: Contradicts his earlier testimony.

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BY MR. NICHOLAS:

Q. Okay.

A. I believe -- well, I don't believe. What I did is I directed people to look for me on my behalf, and I gave them the types of documents and the types of information I would need to form my opinion.

It wasn't that only -- so if I understand your question, you are trying to say that they only funneled to me certain documents to form my opinion, and I directed them to look for documents in certain areas to meet my objective to give an opinion.

Q. Okay. And after you directed them to look for those documents and provide them, you were dependent on them to point to the documents that you would ask for, right?

A. In some cases, yes, sir, or I would try to look for them and find them myself.

Q. Right. But in the instances where when you were asking them to, like, find the documents and send them to you, you were necessarily dependent on them -- you were relying on whatever they did send you as

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the stuff that you had asked for, correct?

A. Just so -- and I'm going to answer, but just so I can clarify my answer. So if I said I would have wanted to see all suspicious orders policy for a certain company, it was my belief that somebody looked and helped me locate those documents and sent them to me.

Q. Okay. I understand.

So let's go back to 2004-2005.

(Whereupon, Deposition Exhibit Rafalski-7, 10/25/04 CSRA Memo w/Attachment(s), ABDCMDL00315829 - ABDCMDL00315861, was marked for identification.)

BY MR. NICHOLAS:

Q. This will be marked as Exhibit 7.

A. Before I look at this, can I make just a clarification?

Q. Uh-huh.

A. So during my training in 2004, I went to the only facility -- we had a couple of offsite visits to registrants, and it's my belief that I think it was some kind

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of a cough syrup manufacturer, but I just wanted to make that clarification. I don't think it was an AmerisourceBergen facility.

Q. All right. Can you look at what has been marked as Exhibit 3 -- I'm sorry, Exhibit 7.

A. Yes, sir.

Q. This is an internal AmerisourceBergen memo to its distribution center managers and compliance coordinators from CSRA. It is dated October 25th, 2004, and the subject is: ABC Awarded DEA Certificate of Appreciation.

Do you see that?

A. Yes, sir.

Q. Okay. And the first paragraph reads: As many of you already know, CSRA regularly provides training for diversion investigator trainees from DEA's Quantico, Virginia training academy. The training takes place at AmerisourceBergen's ABC Richmond distribution center (DC) and includes a tour of the facility.

Does that refresh your memory at all as to the fact that DEA and

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AmerisourceBergen worked together to train DEA diversion investigator trainees?
A. Well, it informs me. I don't know if it refreshes my memory.
Q. Okay. So this is something which you don't recall from your review of the documents; is that right?
A. No, sir.
Q. Okay. And you see the next paragraph that says: At the conclusion of the training on Friday, October 22nd, 2004, DEA presented ABC with a certificate of appreciation in recognition of ABC's contributions to Drug Enforcement -- DEA's training program. Steve Mays accepted the award on behalf of AmerisourceBergen.
Do you see that?
A. Yes, sir.
Q. Were you aware that Steve Mays worked closely with the DEA in putting together and making presentation -- presentations to DEA's trainees in 2004?
A. No, sir.
Q. Okay. Did you read Steve Mays' deposition? It doesn't appear you did from

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the list that you provided, but I'm giving you a chance to say that you did.
A. No, I do not believe I did.
Q. Okay. And let's just go on to --
A. We're done with this?
Q. I think we are. I want to go on to the next document. Yeah. Okay. We'll do one more of these documents.
(Whereupon, Deposition Exhibit Rafalski-8, McCarty Memo to Mays w/Attachment(s), ABDCMDL00315862 - ABDCMDL00315881, was marked for identification.)
BY MR. NICHOLAS:
Q. This is Exhibit 8. Now, this is a letter that I believe -- it's hard to know the date, but the date had to be in or around March 9th of 2005 because that date is referenced in the letter.
So just take a look at the letter and then I'll ask you a couple of questions about that. And also look at the attachments because I'm going to ask you a few questions about those as well.

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(Document review.)
A. Okay.
BY MR. NICHOLAS:
Q. All right. Let's start with the cover letter. It is a letter to Steve Mays. The date isn't clear, but it was probably sent sometime in March of 2005. Sent from John R. McCarty, special agent in charge, from the U.S. Department of Justice Drug Enforcement Administration Office of Training, Quantico.
Do you see that?
A. Yes, sir.
Q. Do you know John McCarty?
A. I know who he is, and I think I met him, but to say do I know him? No more than just an introduction and knowing the name.
Q. What do you know of him? I mean, you say you know who he is. Who is he?
A. I believe -- I believe that when I went through the training, he might have been the assistant special agent in charge.
Q. Okay. I guess that was going

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to be my first question.
This letter refers to the fact that DEA trainees are scheduled for a visit to Bergen Brunswig in March of 2005. It says: Approximately 40 employees participating in the tour will be arriving by bus at approximately 9:00 a.m. and will depart your facility at approximately 12:00 noon for the return trip to Quantico.
So my first question is: Were you one of these -- were you one of these guys?
A. No, sir.
Q. Okay. And you'll see above that, Mr. McCarty is writing to Mr. Mays. Mr. Mays is the manager of regulatory affairs for AmerisourceBergen, and he says: I appreciate your cooperation and I'm certain that the visit to your distribution plant will be a valuable learning experience for your students -- for our students.
Do you see that?
A. Yes.
Q. And then the attachment appears to be a --

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MR. FULLER: Counsel, just for the record.
MR. NICHOLAS: Yeah.
MR. FULLER: Clearly, ABC Bates-numbered them chronologically, but there's no indication in this letter from the DEA that this document -- or that there's any attachment.
MR. NICHOLAS: Okay. I understand.
MR. FULLER: Are you --
MR. NICHOLAS: There may or may not have been -- then perhaps -- I mean, my working assumption is it was an attachment to the letter.
MR. FULLER: Okay. So that's what you're asserting.
MR. NICHOLAS: I am asserting it. I don't have iron-clad proof.
MR. FULLER: Okay. There's no date on the presentation here.
MR. NICHOLAS: I know. I'm not sure it matters that much, though, for the purposes of my questions.

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MR. FULLER: Okay.
BY MR. NICHOLAS:
Q. Do you see that, in fact, a PowerPoint presentation was put together -- was put together and presented by AmerisourceBergen in cooperation with the Drug Enforcement Administration? I'm looking at page -- the first page of this presentation and the very first slide.
A. I don't have any knowledge whether or not it was presented.
Q. Do you have any reason to believe it was not presented, this slide -- here's what the slide says for the record --
A. No, I could answer on both the negative and the positive.
Q. I'll read it anyway.
A. I have no knowledge that it was or it wasn't presented to the --
Q. Any reason to believe it was not?
A. No.
Q. Okay.
A. Same as there's no reason to believe that it was.

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Q. Well, do you think that it's likely that this presentation was put together with these PowerPoint slides that the first slide says Presented by AmerisourceBergen Corporation in cooperation with the Drug Enforcement Administration, and the presentation never took place?
A. Well, I think you're asking me to draw that conclusion, and I don't want to be argumentative, but this letter says about an intended meeting or something that was going to occur. I don't know that the actual training ever occurred. I wasn't at the training. I don't have knowledge of it.
So, I mean, I think that's a reasonable -- I wouldn't even say reasonable. I guess that's one conclusion you can draw, but the same as maybe the meeting never occurred. I just don't want to agree to something that I don't know too much about.
Q. I understand. Would it help you to know -- would it help you if you knew that Mr. Zimmerman testified in his deposition that the meeting occurred and that he, in fact, made a presentation to Quantico

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trainees at the AmerisourceBergen facility and used this PowerPoint? Would that be a helpful fact?
A. It would be a fact I would consider. I don't know that --
Q. But you still wouldn't necessarily believe him?
A. Well, I guess I'd like to read the deposition versus -- not that I don't believe you.
Q. No, no, no. I'm just saying if that is what he said in the deposition, would you -- would you still not be sure you believed him?
A. No, I probably would not be sure that I wouldn't believe him.
Q. In other words, you would believe him?
A. Yes, I had no reason to not believe that he would make something up.
Q. So you'd believe him? You believe him?
A. Well, yeah, but just so we're clear, the first question, I mean, the first question of whether or not I just believed

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this happened, and without --
Q. No, no, no, we evolved from that to this set of questions.
A. Okay. All right.
Q. Okay.
A. I guess if there was some deposition that discussed it and said it occurred --
Q. Yeah.
A. -- I'd have no reason not to believe that that actually occurred.
Q. Okay. Let's just work on the assumption that it occurred, for the sake of the questions, all right?
A. Sure.
Q. Do you agree -- do you see that as put together, this was a presentation that was to be made by AmerisourceBergen in cooperation with the Drug Enforcement Administration? I'm looking at the first slide.
A. Yes, sir.
Q. Okay. If you look at the third slide, it says: Statements of Goals. The goal of this program is to provide the

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participants with an overview of the pharmaceutical (drug) wholesale industry and the wholesalers' compliance with 21 CFR 1300 to the end. In addition, we will provide examples and methods of standard operating procedures of a full-line pharmaceutical wholesaler in an attempt to educate and thus enhance and build on the good working relationship between the industry and DEA.
Do you see that?
A. I do.
Q. Do you agree that there was a good working relationship between the industry and DEA in 19- -- in and around 2004?
A. I would say based on this program and the collaborative effort, that that would be a good definition of a good working relationship. I think this is an important part of communications and contact and cooperative efforts between the DEA and industry. I'd like to just elaborate a little bit why this -- why I say that and why this is important.
Because as a trainee, it's --

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the diversion investigator's job is a pretty complex -- it's a very complex job, and to get in just a basic understanding of what happens at a distributor facility or one of the larger facilities, manufacturers and distributors, it's a valuable opportunity for somebody to go on site and just get an understanding of just the totality of everything that happened.
So I agree with that statement. I think it's a -- well, it would be important for on-hand or -- I don't know that the actual -- it was an actual practical training, but it gave an exposure to the industry.
Q. Well, we can agree on that.
Can we agree that it's something -- that working with the DEA in this fashion is something that AmerisourceBergen should be proud of?
A. I think the DEA should be proud of it too.
Q. I agree with that.
Can we agree that it's also something that AmerisourceBergen should be

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proud of?
A. Sure.
Q. Okay.
MR. NICHOLAS: Just give me 30 seconds or maybe one minute, see if I have any other questions.
THE WITNESS: I'm not going to hold you to that.
MR. NICHOLAS: The bad news for you is that I'm not the only person asking you questions today.
THE WITNESS: I'm sure not everyone came here to watch you and I discuss these matters, so I don't find that surprising.
MR. NICHOLAS: Okay. Can we go off for one minute? I'm going to be very fast here.
THE VIDEOGRAPHER: Going off the record, 2:34 p.m.
(Recess taken, 2:34 p.m. to 2:35 p.m.)
THE VIDEOGRAPHER: Back on record, 2:35 p.m.
///

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BY MR. NICHOLAS:
Q. Are you aware that AmerisourceBergen worked with the DEA again in 2007 to develop an enhanced suspicious order monitoring program?
(Document review.)
A. Well, I'm not sure. If you want to give me a clarification. When you say they worked with DEA, was that in response to an administrative action, or is it some kind of collaborative effort? Is there --
BY MR. NICHOLAS:
Q. Couldn't be both?
A. Well, I think it's -- it could be both, but I think what -- the causation would be a little different if it was --
Q. I'm not asking about the causation, but I will if you want.
So the DEA, as you referenced in your report, suspended the AmerisourceBergen's Orlando facility in, I think, April of 2007, correct?
A. Right.
Q. And that facility was reopened

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I believe in June of 2007.
A. Uh-huh.
Q. Correct?
A. Yes.
Q. Okay. And between April and June of 2007, AmerisourceBergen worked with the DEA on the elements of the program that would be going forward following the reopening of the facility, correct?
A. I'm not comfortable with the term "worked with."
Q. Really?
A. It could have been an obligation as part of the MOA, so --
Q. Well, whether it was an obligation or not, and I don't believe it was, but even if it was, they still worked -- why does that change whether they worked with them or not?
A. Well, I guess it's a clarification on "work with." I guess in my capacity, if I go back to my experience, I've worked with a lot of DEA registrants on certain matters, but it becomes a little more sensitive to me is if I'm going to agree to

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something that would be specific to designing a suspicious order system.
So just to say is it shocking they worked with them? No, it's not, but I guess I'd need to know what context you're speaking of.
If it's something that's detailed in an MOA that requires them, the DEA, to do it, I guess they would work with them, but I guess it would be at the direction of the memorandum of agreement.
Q. And are you aware that before ABDC entered into a settlement agreement with the DEA on June 22nd of 2007, ABDC, which is AmerisourceBergen Drug Company, worked closely with the DEA to develop a new suspicious order monitoring program before the MOU?
A. So the way that you had stated that question, I would have to say I'm not aware of that.
Q. Okay. Do you know who Mike Mapes is?
A. I do, yes, sir.
Q. Were you aware that Mr. Mapes

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worked -- from the DEA, worked closely with AmerisourceBergen to develop its program in 2007?
A. I'm aware that Mr. Mapes -- well, my awareness of what Mr. Mapes' interaction with ABDC was, I believe there was an industry conference presentation around that period of time, but I'm not -- I don't have any recollection of personally or reviewing records that he was working with them to develop changes or improvements to their suspicious order system.
Q. Well, there was some testimony in Steve Mays' deposition about just this subject, but as you've already told us, you didn't read Mr. Mays' deposition, correct?
A. I don't recall reading it, no, sir.
Q. Okay. Well, let's just talk about that conference for a minute. The Diversion Control Division of the U.S. Department of Justice I believe sponsored a conference with the pharmaceutical industry -- it was called a pharmaceutical industry conference -- in

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September of 2007 in Houston.
Are you familiar with that?
Did you attend it, I should say?
A. I did not attend it. I'm familiar that the conference occurred. That came up in one of my other cases that I investigated.
Q. Okay. And were you aware that at that conference in September of 2007 in Houston, Texas, Mike Mapes from the DEA and Chris Zimmerman presented to the entire industry on suspicious order monitoring programs? Are you aware of that?
A. Just for clarification, I'm aware that the industry training occurred and that there was the discussion or there was some presentation on it. I don't know the extent of the presentation, but I know there was some presentation in regards to responsibilities in regards to suspicious order systems.
Q. Are you aware that as part of the presentation, Mr. Zimmerman from AmerisourceBergen talked about ABDC's program, new suspicious order monitoring

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program or enhanced program to the entire industry?
A. I believe that somewhere I had reviewed -- or I don't know if it was my previous employment experience or if it was something I reviewed as part of my opinion, but I was aware that it occurred.
Q. So in 2007 at a DEA-sponsored conference, Mr. Zimmerman from AmerisourceBergen was on stage with Mr. Mapes presenting a description of AmerisourceBergen's suspicious order monitoring program to the entire invited industry group, correct?
A. I don't have any information to disagree or agree with you, so -- I don't know that they stood on stage together. I wasn't there. So if that's how you represent it, I don't have any knowledge to disagree, but...
MR. NICHOLAS: Okay. Let's mark one more exhibit.
(Whereupon, Deposition Exhibit Rafalski-9, 9/11-12/07 Meeting Agenda, DEA Diversion Control Division

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[No Bates], was marked for identification.)
BY MR. NICHOLAS:
Q. Exhibit 9. This document, Exhibit 9, Mr. Rafalski, is a brochure, I guess, or a publication -- I don't know what you want to call it -- sent around -- or describing the upcoming -- what is then an upcoming pharmaceutical industry conference. It's the one we've been talking about. It took place on September 11th and 12th, 2007 in Houston, Texas.
Do you see that?
A. I do.
Q. And it's got like a one, two -- it's got a two-day agenda, Tuesday and Wednesday, the 11th and the 12th?
A. Yes, sir.
Q. And there is a section on suspicious orders on the agenda on page 1 -- you know, on day one.
And if you turn to the second page of this document, you can see the description about the suspicious orders.
Do you see that?

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A. Yep.
Q. Okay.
A. Yes, sir, about halfway down.
Q. Yeah. And basically, this description just -- this blurb describes -- you know what, this makes it pretty clear that this is a report of what happened at the conference. It was after the fact.
Because it describes how Mr. Mapes, the chief DEA regulatory section, and Chris Zimmerman, vice president, corporate security and regulatory affairs, AmerisourceBergen, updated, past tense, attendees on when suspicious order reports should be submitted to authorities, and then it goes on.
So does this document provide you a little more comfort that what I'm representing to you about the fact that Mr. Mapes and Mr. Zimmerman made a joint presentation to the group, the entire group is, in fact, true?
A. It does. And it also jogs my memory. There was a particular slide that occurred during this conference in regards to

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suspicious orders, and it was whether or not the shipping requirement -- it wasn't called the shipping requirement, but this particular slide had language similar to the 2006 Rannazzisi memo, and that was once you identify a suspicious order and continue to ship the suspicious order without dispelling the suspicion, it would be attributed to diversion.

And I remember that slide. It came up in a different investigation. So way back at this time when this occurred, right after, I think -- and I don't remember exactly what year.

I think 2009 or '10, it -- this came to my attention and there was a lot of discussion about that -- the meaning of that particular slide because there wasn't a language where even back then the industry was saying that DEA should just say stop shipping an order, but what they would say is if you failed to stop, it was a failure to have effective controls against diversion.

Q. So it was kind of confusing to the industry?

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A. Well, I don't know if it was confusing to the industry. It's the same thing I've been saying all along. If you report a suspicious order, then ship it --

Q. Well, they had a slide about it. I guess somebody thought it was worth showing people because they needed a slide because it was perhaps not as clear as you're saying it was.

A. No, I think it was stating the same thing that Mr. Rannazzisi stated. So why I remember it is in the course of how it was used in this case, someone alleged it had a different meaning. So we had the same discussion back then about whether it meant to stop a shipment or not.

Q. So you're saying this jogged your memory. Like -- wait, though, does that mean that you were at this presentation?

A. No.

MR. FULLER: Form.

BY MR. NICHOLAS:

Q. Oh, you just saw the slide later --

MR. FULLER: Form.

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BY MR. NICHOLAS:

Q. -- or something?

MR. FULLER: Form to the prior three questions. Y'all just give me a little bit of a pause if you don't mind.

THE WITNESS: Yes, sir.

A. It jogged --

BY MR. NICHOLAS:

Q. You weren't at this --

A. I was not.

Q. Okay. So let's get back to the question I was asking about. I appreciate the detour there, but what I'm really wanting to know is whether this provides you -- and I think you answered yes -- provides you with some comfort that my telling you that this presentation occurred and that Mr. Mapes and Mr. Zimmerman jointly presented to the entire industry --

A. I could draw that conclusion by reading these two paragraphs.

Q. Okay. Give me one more minute, and I believe I'm going to --

MR. FULLER: That's what you

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said last time.

MR. NICHOLAS: I know. Yeah, I'm one of those guys, you know. All lawyers are the same.

MS. QUEZON: But it probably has been an hour if you want to take five minutes.

MR. NICHOLAS: Has it been an hour?

MR. FULLER: Yes.

MR. NICHOLAS: Let's take five minutes. Good chance I'm done.

THE VIDEOGRAPHER: We're off the record. The time is 2:51 p.m.

(Recess taken, 2:51 p.m. to 2:59 p.m.)

THE VIDEOGRAPHER: We're back on the record at 2:59.

MR. NICHOLAS: Mr. Rafalski, that's all the questions I have at this time. I appreciate your time. Thank you for answering my questions, and in an incredible abundance of caution, I'll reserve the remote right to come back and ask you a few more

questions later, but I really think that's unlikely. I don't think I'll have any more.

THE WITNESS: Thank you very much. Pleasure to meet you.

MR. NICHOLAS: Same.

EXAMINATION

BY MR. PYSER:

Q. Good afternoon, Mr. Rafalski. My name is Steve Pyser. I'm going to be asking you some questions today for Cardinal Health, okay?

A. Okay.

Q. Have you ever visited any Cardinal Health facility?

A. No, sir.

Q. Have you ever interviewed any Cardinal Health employee?

A. No, sir.

Q. You stated earlier today that in your work to date on this case, going back about two years until today, including the preparation of your report, you'd spent about 400 hours roughly on the case?

A. Roughly, yes, sir.

Q. Now, your report covers about a dozen -- I think actually 13 different defendants. Can you tell me approximately, of that 400 hours, how much of that time did you spend reviewing documents and depositions related to Cardinal Health?

MR. FULLER: Form.

A. It's difficult for me to answer, to just give you a specific number of hours. I could say significant, but I know that's not a full answer.

Over the last -- probably beginning in the early fall, up until the day I submitted my report, those were -- the majority of hours in regards to the 400 were spent during that time frame researching, preparing the report, reading depositions and looking at documents.

BY MR. PYSER:

Q. Maybe my question was unclear.

I understand that you spent a large portion of the 400 hours looking at documents and preparing your report.

A. Yes.

Q. I'm asking to break it down by

defendant a little bit.

A. Oh, okay.

Q. So if there's 13 defendants, is it roughly spread evenly, divided by 13, you get a rough approximation?

A. Well, I think I spent a little more time on the distributors until I did the -- instead of the manufacturers. I would say I probably spent more time in totality and individually in -- as far as just at the distributors.

I would probably say pretty equal except with Henry Schein, because that's a smaller distributor and there was less documents and less information to review.

Q. So for each of the larger distributors, we're talking something in the range of 50 or 60 hours each; is that fair?

A. I guess that could be a possible --

MR. FULLER: Object to form.

A. I guess it could be a possible approximation.

BY MR. PYSER:

Q. Have you ever conducted a cyclic investigation of a registrant?

A. Numerous times, yes, sir.

Q. In any of those investigations, did you review a distributor who sent DEA excessive purchase reports on a monthly basis?

A. No, sir, never.

Q. Did you ever conduct a cyclic investigation of Cardinal Health?

A. No, sir.

Q. In the course of your work preparing for this case, did you review the results of any cyclic investigations of Cardinal Health?

A. So the way I'd like to answer that is that I reviewed documents that -- communications intercompany that cyclic said occurred or regulatory investigations, but I didn't review the actual documents of the DEA or of the actual conducting of the investigation. So I hope that answers your question.

I know they occurred and I know there were some documents where there was an

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internal assessment of what the DEA did, but I never reviewed like the actual DEA investigations.

Q. In the documents you did review of the cyclic investigations, did you ever see an indication that DEA had stated that Cardinal Health's practice of sending monthly ingredient limit reports to DEA was improper? Did you ever see that indicated?

A. No, sir.

Q. You state in your report that Cardinal's ingredient limit report system, this monthly report, was premised on guidance from the 1998 DEA report; you call it the Reno report.

Do you recall that?

A. Yes, but I don't say that. I think I provide an opinion because I believe some Cardinal representative said that.

Q. You're aware that Cardinal Health had the same system in place before the Reno report came out?

A. Yes, sir.

(Whereupon, Deposition Exhibit Rafalski-10, 10/98 Report to the U.S.

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Attorney General, CAH_HOUSE-002207 - CAH_HOUSE-002298, was marked for identification.)

BY MR. PYSER:

Q. I'm showing you a document that's been marked as Exhibit 10. Is this the Reno report that you refer to in your report?

MR. FULLER: You provided us copies.

MR. PYSER: As we go down through the day, there will be less copies from each person asking questions.

A. Yes, sir.

MR. FULLER: Now I don't feel so bad that I didn't always comply with the protocol.

BY MR. PYSER:

Q. Okay. If you turn with me to -- using the pages in the bottom right, the Bates pages, there's a page CAH_HOUSE-002230.

A. Okay.

Q. Now, you had stated in your

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report that the suspicious order monitoring system recommended in this Reno report from 1998 was for List 1 chemicals. Do you recall that conclusion or opinion?

A. Yes. Yes, sir.

Q. I want to direct you to the actual report at Bates page 2230. Under B1, Wholesaler Distributors, it states that those in the wholesale drug distribution supply chain who are able use the DEA-approved suspicious order monitoring system in use by wholesale drug distributors for controlled substances.

Do you see that statement?

A. Yes, sir.

Q. So at the time in 1998, you agree with me that there was a DEA-approved suspicious order monitoring system in use by wholesale drug distributors for controlled substances?

A. No, sir. I agree that that's what this statement says, but this is a task force combined of industry members and there were some DEA officials on there, one -- one diversion investigator or someone from the

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diversion unit. And so I'm not in agreement -- and I see this is what the document says -- that that's an accurate statement.

Q. So even though it's on a page with letterhead that says United States Department of Justice, Drug Enforcement Administration, you don't believe it's an accurate statement?

A. I do not.

Q. This is six years before you began your career at DEA, correct?

A. Yes, sir.

Q. So you weren't communicating with anyone at DEA about this task force at the time of the report in 1998, were you?

A. No, sir.

Q. It goes on to say --

A. Can I just clarify that?

Q. No.

A. Okay.

Q. It goes on to say --

MR. FULLER: Go ahead. You can clarify your answer.

A. So just for clarification, and

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I had testified earlier, but I understand that each person is different. So at the time that this statement was made in this publication, which I don't believe it was actually acted on. It was recommendations. I just want to go back to the DEA manual was in place in -- the 1996 DEA manual that would be in conflict with that particular statement.

BY MR. PYSER:

Q. This document was --

A. '98.

Q. -- published publicly in 1998, correct?

A. Yes, sir.

Q. And are you aware if in 1998 anyone from DEA made a public statement that said actually this report to the U.S. Attorney General is wrong, it has an incorrect statement? Are you aware of any statement like that from DEA?

A. I am not aware of any statement like that, no.

Q. The second paragraph on page 2230 says: This is basically what is

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done for Schedules II through V controlled substances.

Do you see that?

A. Yes, sir.

Q. Okay. And what's being done by -- what the report states is being done for controlled substances on Schedules II through V is a DEA-approved suspicious order monitoring, correct?

A. As I stated earlier, I don't agree with that.

Q. But it is what the report states?

A. That is what the reports states.

Q. And if you go a little bit further in the report to Bates page 2247, it's a document that again, at the top of the document it says United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control.

Do you see that?

A. Yes, sir.

Q. Okay. At the top it says: Suspicious order reporting system of 1998 for

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use in automated tracking systems.

Correct?

A. Yes, sir.

Q. And it begins by saying: The current calculation being used for List 1 chemicals on Schedule II through V controlled substances.

You see that statement?

A. I see that statement.

Q. Okay. So according to this document, in 1998, six years before you arrived at DEA, there was a calculation being used for Schedule II through V controlled substances?

A. Well, I'm going to repeat my same answer. This was an advisory committee that put this document together. I acknowledge that it's on Department of Justice letterhead, but I'm not aware of ever seeing any approved DEA approval of any system.

And I acknowledge that the document says that, but later on it specifically talks about Schedule II or Schedule III through Vs that contain List 1

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chemicals.

And when I read the document, the totality of the document is about List 1 chemicals, and --

Q. Correct. The totality of the document --

MR. FULLER: Let him finish his answer, Counsel. Let him finish his answer.

MR. PYSER: Well, he's not answering my question.

MR. FULLER: Well, you may not like the answer you're getting, but he's going to finish his response.

Go ahead.

MR. PYSER: If he's wasting time, I reserve my right to come back for more time.

MR. FULLER: Great.

Go ahead, Mr. Rafalski.

A. And so the totality of this document was in response to the new methamphetamine act and the pseudoephedrine -- making pseudoephedrine a List 1 chemical. So, you know, to me, the

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critical statement here is in 4, the note under Section 4.
BY MR. PYSER:
Q. Sir. I'm not disagreeing with you --
A. Okay.
Q. -- that this document was prepared related to the Comprehensive Methamphetamine Control Act of 1996, and what it's saying is that they're going to introduce procedures for List 1 chemicals that are like those already in place for controlled substances on Schedule II through V. Isn't that what the document is saying?
MR. FULLER: Object to form.
A. Well, what the document says to me is that if registrants, distributors have electronic systems, that a registrant should consider monitoring List 1 chemicals utilizing that same electronic system.
BY MR. PYSER:
Q. And it actually speaks at the bottom of this page to electronic systems, and what the Office of Diversion Control says in 1998 is: Using a computer to manage and

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report on high-volume transaction business activities with extremely short order cycle times receipt to delivery, is the only viable cost-effective methodology for the reporting of orders which may be considered excessive or suspicious.
That's what they said, correct?
A. That's what this statement says. That's what the committee placed in -- that's what the statement says.
Q. And nowhere in this 1998 suspicious order reporting system that you see on page 2247 is there anything about stopping shipments of Schedule II through V controlled substances. That's not on this page, is it?
A. Which page are you referring to?
Q. Page 2247, Exhibit 2, Suspicious Order Reporting System of 1998.
A. There's nothing on that particular page.
Q. Should distributors rely on information they receive from DEA?
A. So my general answer to that

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question would be yes, but I guess I'd have to say it would depend on the topic and the type of question and the information they receive.
Q. Is being told -- strike that.
If a distributor is told you're doing the right things and heading in the right direction with respect to a suspicious order monitoring program, is that an implicit approval from DEA of the suspicious order monitoring program that that distributor is using?
A. Well, I think it could be taken as an implicit approval, but then to know the whole totality of what occurred to just have that one statement, it could be a simple aspect of the system.
So from -- and so I'll agree but I -- but it depends on what the topic is and what the question is and the complexity of it.
Q. So if someone at DEA reviewed a suspicious order monitoring system and told a distributor you're doing the right things and heading in the right direction, that's

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implicit approval of the system they just reviewed, correct?
A. It is, but again, in my experience and in doing cases, I've had other cases where a diversion investigator would make a similar type comment to a registrant and the system was not satisfactory.
So --
Q. Does that mean the diversion investigator doesn't know what they're doing?
A. That could be one possible explanation. I can't --
Q. How many diversion investigators do you believe work at DEA and don't know what they're doing?
MR. FULLER: Object to form.
A. I have no idea, sir.
BY MR. PYSER:
Q. While you were there, did you believe your colleagues were competent?
A. Would the universe be all diversion investigators? I would have to say no, because I know of a couple that would make statements that were not within the guidance or the guidelines of what DEA would

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expect in regards to approving and commenting on suspicious order systems.
Generally speaking, yes.
Q. How about Kyle Wright?
MR. FULLER: Object to form, outside the scope.
A. I've worked with Kyle Wright and I've been present at one of his presentations. I believe he's highly competent. Sometimes I believe that he doesn't articulate his subjects very well. I believe his knowledge base is high, but I'm not sure that I would say that his articulation of some of that knowledge is very well.
BY MR. PYSER:
Q. Did you ever file a complaint while you were at DEA or complain to a supervisor that you believed things that Kyle Wright was saying in his presentations were inappropriate?
MR. FULLER: Object to form. Don't answer that question based on your Touhy authorization. Way outside the scope, Counsel.

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MR. PYSER: Are you going to refuse to answer that question?
THE WITNESS: Yes, sir, on the advice of my counsel.
BY MR. PYSER:
Q. You're relying here today on your experience at DEA, correct? That's why you consider yourself an expert?
A. That's -- yes, sir, that's one of my strengths, that my experience and then the results of my experience, the Masters case, the subsequent ruling, the Mallinckrodt case.
Q. In your report around page 48, you describe Cardinal Health's suspicious order monitoring system as having two operational aspects. So the first aspect you talk about is ingredient limit reports?
A. Yes, sir.
Q. And the second one are reports of excessive orders, correct?
A. Yes, sir.
Q. The ingredient limit reports, those are submitted on a monthly basis from each Cardinal distribution center to the

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local DEA office, correct? That was the practice at the time?
A. Yes. Post distribution of the drugs, at the conclusion of a month, they would submit the report, yes, sir.
Q. And DEA would receive that report on a monthly basis post distribution of the drugs, correct?
A. I guess I would make that assumption. I never saw them. I wasn't there at some of the time period. I've never received them personally, but I don't have any information to not believe that statement.
Q. Where you were was in Detroit and Cardinal Health didn't have a distribution center in your region, correct?
A. That's correct.
Q. Now, you list some of the ingredient limit reports in your report, correct?
A. Yes, sir.
MR. PYSER: Let me mark this one for you.
(Whereupon, Deposition Exhibit

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Rafalski-11, Ingredient Limit Report, CAH_MDL_PRIOROD_DEA07_01465435 - CAH_MDL_PRIOROD_DEA07_01465712, was marked for identification.)
BY MR. PYSER:
Q. I'm marking Exhibit 11. This is the first ingredient limit report that you mentioned in your report for this case. This is a document -- it's a couple hundred pages long?
A. It is.
Q. And this is one month's report from one distribution center, correct?
A. Yes, sir.
Q. So you can multiply this out in terms of the information that Cardinal Health is providing to DEA on a monthly basis for each of its 20-some-odd distribution centers, correct?
A. Yes, sir.
Q. Now, I want to draw your attention to Bates number 1465496. Are you there with me?
A. I am.
Q. Okay. Now, on that page

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there's a run date, so the date of this report, of September 4th, 2005, right?
A. Yes.
Q. Okay. And it labels itself an ingredient limit report, and looking again at that Bates page I gave you ending 496?
MR. FULLER: I'm sorry, say the Bates number again.
MR. PYSER: Ending in 496.
MR. FULLER: Oh, I got it, sorry.
BY MR. PYSER:
Q. It has factor used of 4.0.
Do you see that?
A. Yes, sir.
Q. Okay. And underneath that, there's a customer name, the Fredrick County Health Department. And the ingredient? It's about halfway down the page.
A. Yes.
Q. And the ingredient is buprenorphine hydrochloride?
A. Yes, sir.
Q. And it lists the customer total versus the ingredient limit?

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A. Yes, sir.
Q. So the factor that's used, this factor of 4, that's right there on the face of this ingredient limit report sent to DEA, correct?
A. It is.
Q. And to your knowledge, DEA never told Cardinal Health you should use a different factor, use some other factor other than 4?
A. In my research for completing my report and then also based on my experience working there, I'm not aware that anyone ever told them not to use the factor of 4.
Q. Another critique -- you can put the ingredient limit report aside. It's a big document. Get in your way otherwise.
On page 58 of your report, you level a criticism at Cardinal because there's an increase in the amount of oxycodone from the Wheeling, West Virginia distribution center, correct?
A. Yes, sir.
Q. The DEA field office that

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received the ingredient limit reports like Exhibit 11 from the Wheeling distribution center, they would have seen those increases as well because it's right there in the document, right?
A. I don't know what the DEA office that received them would have seen or not seen. I don't know if they would have looked back historically.
I offered this opinion in my report because I believe it's something that Cardinal should have seen.
Q. Okay. So you don't have any reason to think DEA was incapable of looking at the ingredient limit reports like Exhibit 11 and looking at a trend, correct?
A. I don't have any information whether they were or weren't, sir.
Q. Okay. And DEA also receives ARCOS information from every transaction that every distributor makes of a controlled substance, Schedule II controlled substance, including Cardinal, correct?
A. They do, but in a different way. So this -- just so clarification, I

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think our discussion was that this would be received at the -- at the office that would be nearest the distribution center. The ARCOS gets received at headquarters and it's a totally different --
Q. Understood. So --
A. Okay. Just clarifying that.
Q. So DEA has at the local field office, they've got the information about distributions from the ingredient limit reports that are reported by Cardinal because they went over the factor 4.
And then also, at the national office, DEA has the ARCOS report which has every transaction from a distributor to a pharmacy, correct?
A. It has every Schedule II transaction, Schedule III narcotics and one other -- one other category of drugs. It's not all transactions.
Q. So any increases could have been seen in the ARCOS data as well?
MR. FULLER: Form.
MR. PYSER: Let me rephrase the question.

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BY MR. PYSER:
Q. So any increases in the amount of oxycodone being shipped from the Cardinal distribution center in Wheeling to Cardinal's customers could have been seen in the ARCOS data reported to DEA?
MR. FULLER: Form.
A. So --
MR. FULLER: Go ahead.
A. Just a clarification. The ARCOS data gets submitted on a monthly or quarterly basis to the DEA, and it's -- I think they used the term "cleansed," but it's corrected for any potential errors, and then it's deposited into a huge database and it's designed to be queried.
So what you said is potentially true if somebody would -- would query that particular topic, but I just want to make sure that we -- I understand it's not automatically reviewed or there's not a process to do what you said it did.
Of course, any data could eventually be reviewed for any type of information, but that's not how it was

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utilized by the DEA.
BY MR. PYSER:
Q. During this time when you're criticizing Cardinal for an increase in oxycodone shipments, DEA had also increased the quota of oxycodone available in the United States for legitimate medical purposes, correct?
MR. FULLER: Object to form.
If you know.
A. I don't know.
BY MR. PYSER:
Q. You don't know when or if DEA increased the quota for oxycodone in the country?
MR. FULLER: Same objection.
A. I didn't review that information, so I don't know.
BY MR. PYSER:
Q. Do you think that's something as a diversion investigator you should know?
MR. FULLER: Object to form.
A. No, sir.
BY MR. PYSER:
Q. The DEA license held by the

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Wheeling distribution center of Cardinal Health, that license has never been suspended or revoked by DEA, correct?
A. That's a correct statement.
Q. Okay. So we've talked about the ingredient limit reports. I want to go back to the second aspect of Cardinal Health's pre-2007 system you talked about in your report, and that's the reports of excessive purchase orders on a daily basis to DEA before shipment.
A. Uh-huh.
Q. And that's around page 59 of your report.
A. The pickers and packers? Yes, sir.
Q. So Cardinal Health's policies instructed personnel to monitor and identify individual orders that appeared excessive before they were shipped, correct?
A. Yes, sir.
Q. Now, you, in your report on page 59, you list a couple dosage limits for select medications, correct?
A. Yes, sir.

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Q. Now, there are some customers, isn't it true, who are going to consistently order over these limits because they're large customers; isn't that right?
MR. FULLER: Object to form, vague.
A. Well, I guess that is a possibility. I didn't see anything that would not require an employee of Cardinal to follow this procedure that would exempt any type of customers or have them fail to take this appropriate -- or this -- not appropriate -- take this action as required.
BY MR. PYSER:
Q. What the policy says is on a daily basis, cage-involved personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations DEA should be notified if possible before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file, along with the regulatory agency contact form noting any

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specific instructions from DEA.
Correct?
A. Yes, sir.
MR. FULLER: And I don't know what he's reading from, but if you want to pull the policy to make sure he's reading it accurately, you're welcome to do so. I don't know --
MR. PYSER: Counsel, we can drop the speaking objection. He's already answered.
MR. FULLER: No, I won't drop the speaking objections.
BY MR. PYSER:
Q. So let's take an example, the Cleveland Clinic. They're in Cleveland, Ohio. It's a large medical facility.
Would you expect the Cleveland Clinic to order, when they order from Cardinal Health, more than 800 capsules of hydrocodone at a time?
A. I don't really have an opinion either way. It's a possible reasonable assumption, but without seeing the distribution datas or the purchasing

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requests, I don't know.
Q. And you haven't looked at that information. You haven't gotten to that level of granularity in your work?
MR. FULLER: Form.
A. I didn't review the Cleveland Clinic or the ingredient limit reports for specifically looking for the Cleveland Clinic. I focused on the retail or the pharmacies.
BY MR. PYSER:
Q. Do you believe that Cardinal Health should have stopped shipping hydrocodone and other pain medicine to the Cleveland Clinic based on the fact that there were times when the Cleveland Clinic ordered more than 800 tabs of hydrocodone at a time?
A. So how I'll answer that is that this policy was set up by Cardinal and it's in response to how Cardinal identified the scope of the businesses they supply.
So my opinion is based on the policy that Cardinal set up. I didn't set up this policy for them; they did. So if their policy requires them to take an act and

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they've set the limit up at 800 tablets, then unless they modify their policy or they have some exception, I -- this is their policy, and this is what they're requiring their employees to do.
Q. Sir, do you think that it would be appropriate to deny cancer patients at the Cleveland Clinic medication based on this absolute limit? Yes or no?
MR. FULLER: Object to form.
That wasn't the same question.
A. Well, I think to answer that question, if that did occur because they had a defective suspicious order system, they should correct that so that doesn't occur.
But so -- I guess that's a hypothetical that I don't really want to comment on, but the main thing that I want to make sure is that -- on my statement is that this is Cardinal's policy, and this is what they're requiring their employees to do.
BY MR. PYSER:
Q. Sir, where do you get the opinion that there was no flexibility around this policy and Cardinal Health had no choice

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in its policy but to stop shipment of any order above these limits?
A. I didn't see any documents or any policies that gave the employees that flexibility.
Q. You make reference in your -- in your report to the deposition of Steve Reardon.
Do you recall that?
A. Yes, sir.
Q. Did you read Mr. Reardon's entire deposition?
A. I believe I did, yes, sir.
Q. Every page?
A. Well, yes, sir, I believe so.
Q. No one from the plaintiffs' counsel pointed you to certain pages and told you to read those but not others?
A. No, sir.
Q. Did DEA require a particular form or format to report suspicious orders?
A. No. The -- how a suspicious order is reported to the DEA is up to the individual registrant.
Q. So suspicious orders can be

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reported in an ingredient limit report like that, correct?
A. The way they're reported and how they're delivered, that's up to the registrant.
Q. Okay. And if a registrant wanted, they could report a suspicious order to DEA via a phone call, correct?
A. They could. If I was to provide them guidance, I wouldn't recommend that because it's difficult to record and document notification, but there would be nothing in the regulations that would prohibit them from doing that.
Q. If DEA didn't want to receive phone calls, they of course could tell registrants don't call us, correct? They have that ability.
A. Well, if you're asking that based on my last response, that's not what I'm indicating. I'm not saying that I would advocate to tell them don't call me again.
What I'm saying is if they were to call to report a suspicious order, I would take the information and document it and act

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on it, but I would also give some guidance that they may want to deliver the suspicious order report in a way that they have verification.
Q. Did you ever give that guidance to Cardinal Health?
A. No, sir.
Q. At page -- strike that.
For Cardinal Health, are you aware that excessive order reports that are described in your report were often memorialized in agency contact forms?
MR. FULLER: Object to form.
A. I'm aware -- I'm aware that it's a requirement of the policy, also is -- I believe that I've only viewed two completed forms, those agency contact forms, in regards to suspicious -- or suspicious order reports or as far as this activity.
Now, I think that form, if I understand it correctly, is a multiuse form, so it could be used by any contact at different agencies, and the two that I'm speaking of are just in regards to notifying the DEA in regards to orders.

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BY MR. PYSER:
Q. You state at page 60 of your report, quote, I've not been able to locate any reports related to orders in excess of the daily limit for the Wheeling distribution center produced in this matter.
Do you recall that?
A. That's a correct statement. The two that I reviewed I think were a different distribution center.
Q. Okay. How much time did you personally spend looking for agency contact forms from the Wheeling distribution center?
A. I spent considerable time, and then also I think it was part of the requirement that in the -- in the response to discovery to make -- advise on that matter too, so I think if they existed, there would have been other documents that would have indicated they did exist.
Q. Now, if we're talking about the pre-2007 system, we're now here in 2019, so those forms would be 12 or 13 years old at a minimum, correct?
A. Yes, sir.

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Just for clarification, you're talking the agency contact forms or the ingredient limit reports?
Q. Agency contact forms.
A. Okay.
Q. From the pre-2007 time period.
(Whereupon, Deposition Exhibit Rafalski-12, Regulatory Agency Contact Sheet, CAH_MDL_PRIOROD_DEA07_00868973, was marked for identification.)
BY MR. PYSER:
Q. So I'm marking as Exhibit 12 an agency contact form dated February 6th, 2007. Was this one of the forms that you reviewed in your preparation for your report?
A. I -- I don't recall seeing this form before.
Q. Okay. So this is a 2007 agency contact form. The purpose of the contact is reporting excessive purchases of oxycodone.
Do you see that --
A. I do.
Q. -- in the Purpose of Contact section?
And the name, address and

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telephone number of the DEA representative is Jeff Conners.
Do you see that?
A. Yes, sir.
Q. Do you know Mr. Conners?
A. I know the name. I've probably met him once or twice before. But to say know him, I'm not familiar with him personally.
Q. But you know that he worked for DEA?
A. Yes, I -- I think I indicated that, yes, sir.
Q. And the advice that he gave Cardinal Health or the response that he gave Cardinal Health was, quote: Advise to keep sending monthly ILR report.
Do you see that?
A. I see that statement, and I acknowledge that's what the employee wrote down for Cardinal Health. I don't know that that's what Mr. Conner said. And I say that because I've -- in my experience, I have reviewed other documents, even things that I was involved in where people wrote things

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that I didn't say.
Q. Sir, you've not spoken to either Mr. Conners or Ms. Oglesby, who filled out this form, about the form?
A. I have not.
Q. Okay. Yet, you're questioning the veracity of the statement in here?
A. I'm just saying that -- it's not the veracity. I'm just -- and I'm going to acknowledge that is what was said, but I just don't know if that's what Mr. Conners said to Ms. Oglesby.
Q. You don't have any specific reason to doubt that that's what's said?
A. No, sir, just based on my experience that there's been other times when statements were made that weren't -- that didn't -- weren't accurate.
Q. It's true that upon receiving a contact of a suspicious order by phone, DEA also sometimes told Cardinal Health to ship the product that it was reporting, correct?
A. I'm not aware that that ever occurred. Could I ask a question about this?
Do you happen to have the order

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that was required to be attached to it?
Q. I do not have that with me, and it's 13 years ago, so I can't make a representation to you whether or not it still exists.
A. Okay.
Q. Does DEA still have the order?
A. 2007? There -- oxycodone, there would be an ARCOS data entry.
Q. Beyond the ARCOS entry, would DEA have any other record of this transaction?
A. No, sir.
Q. Okay. Would DEA have any other record of this communication?
MR. FULLER: Object to form, outside of scope. Counsel, this is also indicated that it's from the Findlay distribution center, which I don't even believe we've been provided transactional data from the Findlay distribution center.
MR. PYSER: The witness has already testified he looked at reports from outside of --

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MR. FULLER: No, no, I understand that. That brings us back to the issue that we talked about at the very beginning, that most of the distribution into CT1 was from the Wheeling distribution center. This shows that there wasn't, and there were suspicious orders shipped by Findlay.
And I believe Cardinal now needs to supplement with the Findlay distribution data for CT1, for all Findlay distribution data.
MR. PYSER: Mr. Fuller, first of all, it's a speaking objection.
MR. FULLER: I'm going to move -- I'm going to move for that.
MR. PYSER: Let me explain to you that this is not an order placed by a pharmacy in CT1. If you'd read the document, you would see the city is Columbus, Ohio, which is not part of CT1.
MR. FULLER: I see that.
MR. PYSER: So you can take

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your objection and you can put it at a more appropriate time.
BY MR. PYSER:
Q. Sir, do you know a DEA investigator named Chuck Carpenter?
A. No, sir.
Q. On page 61 of your report, you claim that Cardinal Health was delivering oxycodone illegally to a pharmacy known as Ross Westbank Pharmacy.
Do you recall that?
A. What page are you on?
Q. 61.
A. Yes, sir.
Q. Where's Ross Westbank Pharmacy located?
A. I don't know. Let me...
Q. Well, it makes up an entire schedule to your report, Schedule III.
A. I was going to ask to pull those records.
Q. And I'll represent to you that hundreds of times in your very own report, it says Ross Westbank Pharmacy is located in Hudson, Wisconsin.

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A. Okay.
Q. Sir, do you have any evidence to support a connection between the pharmaceuticals shipped to Ross Westbank in Hudson, Wisconsin and use of those pharmaceuticals in Cuyahoga or Summit County?
A. I don't think that appears in my report to attribute the specific distributions. I think it goes into my report to the conduct of Cardinal Health, where the regulations and the compliance department was operated centrally out of the headquarters.
Q. So that's a no to my question?
A. Well, I guess you asked me how I used it. And --
Q. No, I --
A. Could you restate the question? I'm sorry.
Q. Do you have any evidence to support a connection between the pharmaceuticals shipped to Ross Westbank in Hudson, Wisconsin and the use of pharmaceuticals in Cuyahoga or Summit County?
A. No, sir. Just the conduct by

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the Cardinal company.
MR. PYSER: Move to strike everything after "No, sir."
BY MR. PYSER:
Q. Do you know whether Ross Westbank Pharmacy appeared on Cardinal's ingredient limit reports to DEA?
A. I do not know, sir.
Q. Are you aware that DEA has taken the position that there are some legitimate medical sales that occur over the Internet?
A. What would the time frame for that statement be?
Q. Well, you tell me. What's DEA's position about --
A. Well, there is -- there was approval eventually of Internet pharmacies.
Q. When did that happen? Roughly? You don't have to give me an exact date.
A. I really don't want to guess, and I don't have my Code of Federal Regulations here. It was post the Ryan Haight Act or in conjunction with the Ryan Haight Act. I don't want to guess at a year.

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Q. At any time that you're aware of, was there a federal regulation or rule that prevented individuals from ordering noncontrolled substances through the mail, say, blood pressure medication? Is that okay to receive that through the mail?
A. I never received any guidance or training on acquisition of noncontrolled substances pursuant to a prescription, so I don't know the answer to that. I never reviewed it as part of this opinion either.
Q. On pages -- I want to go back a little bit in your report, pages 49 through 50. You list a series of enforcement actions against Cardinal Health.
Do you see that?
A. Yes, sir.
Q. None of the enforcement actions against Cardinal Health that you list in your report occurred in Cuyahoga or Summit County, correct?
A. The purpose for listing these was to demonstrate the failure to maintain effective controls against diversion. I do acknowledge that none of them specifically

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are against the distributions to Cuyahoga County.
Q. Okay. And none of them involve the Wheeling, West Virginia distribution center, correct?
A. That's correct.
Q. On page 52 of your report, you have a paragraph. The first full paragraph talks about a 2005 New York Attorney General investigation?
A. Yes.
Q. And you write: The matter involves, amongst other allegations, price diversion with closed-door pharmacies that engaged in contract pricing.
Do you see that?
A. Yes, sir.
Q. So this New York Attorney General investigation you're speaking about, it involved pharmacies that were buying medication and reselling it to other pharmacies; is that a correct understanding?
A. Yes, sir.
Q. Okay. And that wasn't limited in any way to controlled substances; it was

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the buying and selling of medication more generally than that. That's price diversion, correct?
MR. FULLER: Form.
A. So again, this goes to the conduct of the Cardinal facility, but the answer to your question would be yes.
BY MR. PYSER:
Q. In what you've reviewed related to the New York Attorney General investigation from 2005, you've not formed any opinion that opioids were being diverted to any patient without a legitimate prescription, correct?
A. In my review of that, I don't recall that there was any specific reference to opioids.
Q. Sir, do you have your tax returns from 13 years ago, in 2006?
A. Unfortunately, I would probably answer yes. I believe my wife has my utility records from back at that time. Although I would -- before you ask me again, I would acknowledge that's not the norm.
Q. So most people don't keep their

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tax returns going back 13 years, right, in your experience?
A. Well, I haven't conducted any surveys or asked any people, but generally speaking, people don't keep those kind of records for that length of time.
Q. They may have paid their taxes even though they no longer have the tax returns from 13 years ago, correct?
A. Well, I think in some of those records, I guess retention -- and I'm not sure why there would be a retention because I think there's some law or regulation on how far the IRS could go back and look at your previous tax returns. Seem to think seven years comes to mind.
So there would be no reason to retain them past that period of time as far as I could see, unless that's just what you wanted to do.
Q. So it's your layman's understanding that the IRS tells taxpayers the length of time they need to retain their tax returns in case there's any further inquiry, right?

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MR. FULLER: Object to form.
A. I don't think they tell them that. I think that -- and I don't think the IRS really tells you that either, maybe the law does. I believe in conversations with an accountant, I think they tell you how far back you're required to keep records for a possible audit.
BY MR. PYSER:
Q. In your report, you come to the opinion that if a distributor's unable to locate a due diligence file, say, from 2006, that no due diligence was done, correct?
If you can't put your hands on it today, you make the assumption that nothing was done; is that right?
A. Yes, sir.
Q. Is it possible that due diligence was done back in 2006 or even earlier, but those records weren't retained?
A. Well, my opinion on that matter is if there were no records retained, then there was no due diligence because there's no record of it.
And not just from the

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standpoint of the physical piece of paper, but moving forward even though it's 13 years later, I think there has to be a comprehensive history in a due diligence to make some decisions relative to that pharmacy.

Now, albeit 13 years back is a lot different than the industry is today, but I don't think it would be prudent for any distributor to throw away any record in regards to a pharmacy.

Q. Even a pharmacy that's no longer a customer?

A. Well, I think in regards to that topic, the -- depending on the scenario, if it was a terminated or this customer no longer wanted to do any business with Cardinal, that doesn't mean they could always come back and reapply to be a customer again.

And I think that's one of the critical examples of why you need to retain that, because you would be starting all over again, and you're negating the history, either positive or negative, of the work you did in regards to that registrant.

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Q. When a pharmacy closes its doors, let's say a pharmacy goes out of business, at that point is a distributor free to get rid of the records about that pharmacy or do they have to keep it even after that point in your view?

A. Well, there's no regulatory guidance, the maintenance of effective controls. I guess if you went to the extreme and the owner pharmacist died, but if he -- if he just closed his doors and he moved on and he might potentially open another company, I would say, if it was my decision as a registrant, I would keep the record.

Q. When you were performing cyclic investigations -- is it an investigation or an audit? What's the right term?

A. Well, some people call them cyclic. Some people call them work plans. Some call them regulatories. It goes by all those different names.

Q. So when you were visiting a distributor in your job working as a diversion investigator, did you tell the distributors you visited that it was your

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expectation that all records related to pharmacy due diligence would be kept indefinitely?

A. I believe I would consistently discuss that. Saying that those aren't required records, so that would be a discussion under security, but yes. And I was present -- so there would be my training in regards to the distributor briefings. I was present at a distributor briefing to actually -- because I wanted to learn how they occurred, and Mr. Kyle Wright, we had spoke about him earlier, he would make it clear that -- in pretty common terms that if you don't document it, it doesn't exist.

Q. So while you would inform distributors in your recollection that you believed they should do it, you also told them that it was not a required record to maintain due diligence, correct?

A. I don't know if I would inform them of that --

MR. FULLER: Object to form, misstates his testimony.

A. I don't know if I would

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specifically say it's something they did or didn't do. I would just give them in some matters guidance. It would be a guidance that -- because in most regulatory investigations, I may ask to see some due diligence on a specific customer, and sometimes it would come up when I asked for it that they -- the registrant would tell me that it's not a required record.

So the option was this is -- as part of a work plan or a regulatory investigation, a registrant wouldn't have to show me the due diligence. In that case, I'd have to subpoena.

BY MR. PYSER:

Q. You're one diversion investigator when you were working at DEA, correct?

A. Yes.

Q. Do you know one way or the other whether the diversion investigators who visited Cardinal Health's facilities ever told them about this indefinite record retention policy that you're putting forward in your expert report?

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MR. FULLER: Objection. And remind you of your Touhy obligation. Anything that is internal policy at DEA or communicated while you were on the job is outside the scope of what you're authorized to testify to.

A. I'm not aware.

BY MR. PYSER:

Q. So on page 50 of your report, you have a chart that talks about suspicious orders reported in the CT1 jurisdictions, right?

A. Yes.

Q. Okay. And there's two columns, pre-shipment reporting and then -- on the left, and on the right, post-shipment reporting, right?

A. Right. Yes, sir.

Q. Okay. On the right side, the post-shipment reporting, it's blank until 2005, correct?

A. Yes, sir.

Q. And that's blank there because you know from testimony that Cardinal Health was submitting ingredient limit reports to

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DEA, but we just no longer have those records; is that right?

A. Sir, I believe my report says that I could not find those -- I could not find -- those weren't provided to me and I did not find those reports.

Q. You also reviewed the testimony of Steve Reardon we talked about earlier today, and he said Cardinal Health was sending ingredient limit reports to the DEA beginning in the early '90s, correct?

A. I don't have a recollection of that exact statement in his deposition.

Q. Did you have any reason to believe Mr. Reardon wasn't telling the truth if that is, in fact, what he said?

A. No, I don't have any independent knowledge of not -- whether to believe him or not to believe him.

Q. So on page 50 we have blanks under post-shipment report, where it's unknown, but you filled in zeros on the left side for pre-shipment reports all the way from 1996 to 2012, correct?

A. Yes.

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Q. We talked earlier about these agency contact forms for phone calls to DEA?

A. Yes, sir.

Q. Is it possible that at some point from 1996 through 2012 employees from Cardinal Health may have called DEA before shipping an order that was destined for Cuyahoga or Summit County?

A. If that occurred, I would have an expectation to see one of the agency contact forms.

Q. But knowing that we don't have any agency contact forms from Wheeling, West Virginia, is it possible that people spoke on the phone, but today, from 1996, it's 23 years later, so 23 years later, is it possible a phone call was made but we don't have a record of it?

MR. FULLER: Objection, misstates evidence.

A. So I can only comment on the facts of which I know and what records exist. I don't make comments on hypothetical situations of whether it could have occurred and there was no documentation or it's lost

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or --

BY MR. PYSER:

Q. Well, sir, you do, because you put a zero there instead of leaving it blank like you did on the other side.

So isn't it more accurate that where you don't know, you should leave it blank like you did on the right-hand side, rather than filling in zeros when you don't have any evidence one way or the other? Wouldn't that be a better way to write your report?

A. I guess that's open to your interpretation. I'm confident with putting zeros because I found no documents.

Q. So when you don't know something, you assume it wasn't done in your report, correct?

A. Well, I -- if I don't see a record that I believe should have been retained, then it -- I guess -- I don't know if that's an assumption. It doesn't exist. I can't make an opinion of that a record existed when I don't have any documentation that it did exist.

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MR. PYSER: We've been going about an hour. Let's take a break.
THE WITNESS: Sure.
THE VIDEOGRAPHER: Going off the record at 3:59 p.m.
(Recess taken, 3:59 p.m. to 4:10 p.m.
THE VIDEOGRAPHER: We're back on record at 4:10 p.m.
BY MR. PYSER:
Q. Welcome back, Mr. Rafalski.
A. Thank you.
Q. Directing your attention to page 52 of your report, in the last paragraph, you make a statement that Cardinal Health provided almost preferential treatment to its chain pharmacy accounts as compared to their retail independent customers.
Do you see that opinion?
A. Yes, sir.
Q. And just over on to the next page, you base that on a declaration of Michael Mon?.
Do you see that?
A. Yes, sir.

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Q. And, in particular, if you go to page 13 of this document.
(Whereupon, Deposition Exhibit Rafalski-13, Declaration of Michael A. Mon?, CAH_MDL_PRIOROD_DEA12_00014053 - CAH_MDL_PRIOROD_DEA12_00014081, was marked for identification.)
BY MR. PYSER:
Q. I'm showing you a document now that's been marked as Exhibit 13.
MR. FULLER: Thank you.
BY MR. PYSER:
Q. And on page 13 there's a paragraph, it's paragraph 29. Do you see that?
MR. FULLER: What exhibit number is this?
MR. PYSER: 13.
MR. FULLER: Okay.
You said page 13 as well?
MR. PYSER: Yes. Exhibit 13, page 13.
BY MR. PYSER:
Q. Are you with me, Mr. Rafalski?
A. I am.

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Q. Now, what the paragraph or the page that you cite in your report for that statement says is: In 2009 -- and this is Michael Mon?, Cardinal Health employee in the anti-diversion team, he writes: In 2009, DEA diversion investigator Michael Arpaio raised a question about Cardinal Health's due diligence files on its chain pharmacy customers.
Do you see that?
A. Yes, sir.
BY MR. PYSER:
Q. And a little bit later down, it says: Arpaio told Cardinal Health personnel that he needed to contact DEA's attorney to determine if Cardinal Health's due diligence on chain pharmacies presented any problem. Thereafter, I -- that's Mr. Mon? -- contacted Mr. Arpaio and his supervisor, Ms. Boockholdt, to discuss the question.
Do you see that?
A. Yes, sir.
Q. Okay. And a little bit further down, it says: I told Ms. Boockholdt that we obtained information from CVS's loss

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prevention department which augments the information from Cardinal Health, that Cardinal Health possesses, with respect to any concerns that we identify in CVS orders or stores. Thereafter, neither Ms. Boockholdt nor Mr. Arpaio raised any objections to Cardinal Health's QRA or SOM.
Do you see that?
A. Yes, sir.
Q. Do you know Ms. Boockholdt and Mr. Arpaio?
A. I know who Mr. Arpaio is, and I think I've met him. I know who Ms. Boockholdt is. I probably had some interaction and conversations with her, not in regards to this document, but just in terms of my employment.
Q. And at the very end it states, beginning on the last line: Neither Ms. Boockholdt nor Mr. Arpaio raised any objection to Cardinal Health's QRA/SOM program -- that's their suspicious order monitoring program, correct, SOM?
A. Yes.
Q. -- with respect to chain

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pharmacy customers. DEA's own inspectors have described Cardinal Health's SOM program as one of the best among wholesale drug distributors nationwide.

Do you see that?

A. Yes, sir.

Q. So this is the paragraph you cited in your report, correct?

A. Yes, sir.

Q. Now, Ms. Boockholdt and Mr. Arpaio, who interacted with Mr. Mon? in 2009, that was ten years ago, right, 2009?

A. Yes, sir.

Q. Who's in a better position to understand Cardinal Health's suspicious order monitoring process? Two DEA investigators who spoke to Cardinal Health at the time or yourself ten years later?

MR. FULLER: Object to form, inadequate hypothetical.

A. I don't know what information that either one of these diversion investigators had to cause Mr. Mon? to make this affidavit or --

///

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BY MR. PYSER:

Q. You've never spoken to Ms. Boockholdt or Mr. Arpaio about the statements in this paragraph, have you?

A. No, sir.

Q. You've never seen any statement from Ms. Boockholdt or Mr. Arpaio contradicting the statements in this paragraph, have you?

A. I have not.

Q. In your report, you identify one retail independent customer in Ohio from Cardinal Health and speak about it. It's New Choice Pharmacy?

A. Yes, sir.

Q. And your conclusion or your opinion is that the due diligence file as it exists in 2018 does not sufficiently document certain increases in oxycodone distributions between 2004 and 2008, correct?

A. I'd like to get to that section, but I know my --

Q. Take a look at page 53.

A. -- my report does state that. And I think it also states, if I remember

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correctly, there was three changes of ownership -- actually, let me retract that.

There were three changes of DEA numbers over a period of years, and that was alarming to me, and I would have had an expectation to see some explanation of why that -- those DEA registration numbers changed.

Q. Do you know who owned New Choice Pharmacy, say in 2006?

A. I'm not sure I knew or not. I don't think it -- I don't -- I don't know.

Q. Do you know where the pharmacy is located, was located?

A. Yes.

Q. Where?

A. It was located in a hospital.

Q. In Cuyahoga Falls General Hospital?

A. Yes, sir.

Q. Did you ever visit it?

A. No, sir.

Q. Do you know whether Cardinal Health employees visited New Choice Pharmacy?

A. If they did visit, I don't

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recall seeing any documentation of the visit or results of the visit.

Q. Did you see documentation that Mr. Mon?, the head of Cardinal Health's anti-diversion program, personally visited that pharmacy?

A. I don't have a recollection of that.

Q. Is that something you should have considered?

A. If he visited?

MR. FULLER: Form.

BY MR. PYSER:

Q. Yes.

A. I guess I'd have to see what the results of that visit was. If he -- the purpose of his visit and whether he conducted due diligence and what his notations. I don't recall reviewing any kind of file about documenting the purpose or what occurred during his visit.

Q. If there's a due diligence file that does document Mr. Mon?'s visit, is that something you should have reviewed as part of your opinion?

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A. Yes, sir, I think I would need to consider that. I don't think it would have changed some of the conduct that occurred with -- in regards to the dosage units and the increases, unless there's something specific in there that I'm not aware of.

Q. Do you know whether New Choice Pharmacy ever lost its DEA registration?

A. I'm not aware that it lost its DEA registration, no, sir.

Q. Did DEA ever take any adverse action against New Choice Pharmacy?

A. Not that I'm aware of, no, sir. But that doesn't minimize or alleviate the conduct that I described in my report, whether or not the DEA took action against them.

MR. PYSER: Move to strike everything after "Not that I'm aware of, no, sir."

MR. FULLER: Object to the motion.

BY MR. PYSER:

Q. Did you review a due diligence

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file that made clear that New Choice dispenses from medical staff who are ASAM and pain management certified?

A. I'd like to pull that document, the due diligence file.

Q. Well, if you want to pull a document, we're going to have to go off the record.

MR. FULLER: No, he can do it. You're asking the questions.

MR. PYSER: I asked him a simple question.

MR. FULLER: If you want to give him a due diligence file that's cited in his report, then so be it. He can pull it. You're the one that's not showing him the documents.

Oh, so you had it. Interesting.

MR. PYSER: Enough commentary, Counsel.

MR. FULLER: Nah.

(Whereupon, Deposition Exhibit Rafalski-14, 1/10/08 Brantley Memo w/Attachment(s), CAH_MDL2804_00000606 - CAH_MDL2804_00000618, was marked for identification.)

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BY MR. PYSER:

Q. I'm showing you a document marked as Exhibit 14. This is the file that you reference in your report.

MR. FULLER: Thank you.

BY MR. PYSER:

Q. On the first page it states that New Choice Pharmacy is owned by a hospital, correct?

A. Yes, sir.

Q. On the second page, third paragraph, it states: The account was confirmed as being owned by a hospital, again, and services oncology and hospice patients.

Mr. Rafalski, in your experience, do oncology and hospice patients use more pain medication than the average population?

A. Well, I'm not a physician, but I would have to say in my experience that that would be a logical assumption.

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Q. It goes on to say: In addition, they -- meaning New Choice Pharmacy -- are inspected by the Board of Pharmacy on a monthly basis.

Do you see that?

A. I acknowledge that's what this says, yes, sir.

Q. You don't have any reason to disbelieve the fact that New Choice Pharmacy in this time period was visited by the Ohio Board of Pharmacy on a monthly basis, correct?

A. Well, I would have an expectation that there may be some confirmation of that.

Q. Did you seek the Ohio Board of Pharmacy records for New Choice?

A. I did not.

Q. Would one reason for an increase in orders from a pharmacy be when a pharmacy switches orders over from a secondary wholesaler to a primary distributor?

A. Just so I understand your question, to terminate their receipt of

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product from a secondary and go solely to the primary? Is that --
Q. Not necessarily terminate. Let me try to clarify the question a little bit.
You're familiar with the fact that many pharmacies have more than one distributor?
A. Yes, sir.
Q. So if a pharmacy shifts its orders of both controlled substances and noncontrolled substances from one distributor to another, the distributor to whom those orders are shifting can expect an increase in volume of controlled substance orders, correct?
A. I don't think I understand the question. So the distributions are going to shift from distributor A to distributor B?
Q. Yes.
A. I don't know that that would cause an increase of the purchases.
Q. Well, if -- let's take that simple hypothetical --
A. It would be a new distribution.
Q. If a pharmacy used to order 50%

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of its medication from one distributor and 50% from another distributor, but then starts ordering 100% from, let's call it distributor X.
A. Okay. I understand that hypothetical.
Q. Would you expect that distributor X has an increase in the total volume?
A. So if I looked at a due diligence file and that situation would have occurred, there should be some kind of review or explanation or due diligence investigation that would be indicative of that occurring.
And the other -- the other tool that I might expect to see because there has to be some kind of a review to set a threshold or have an understanding of the legitimate needs of that pharmacy, so I would expect to see some kind of an investigation, maybe obtaining a utilization report or a dispensing report to get a good gauge on the previous patterns of a pharmacy if it's been in existence.
Q. Sir, in your report you don't

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make any reference one way or the other to a shift from secondary distributor to a primary distributor; it's not something that you mention in your report, correct?
A. I do not mention in my report, but I am aware that during the time frame of the three registrations, there was some transfers back and forth between suppliers, multiple suppliers, which would be another concern for me as a diversion investigator or for a registrant because --
Q. Sir, did you --
A. -- that would be --
MR. FULLER: Let him finish his answer.
A. -- that could be another potential way to camouflage or to stop the review of potential diversion.
MR. PYSER: Move to strike the answer as nonresponsive.
BY MR. PYSER:
Q. In addition to New Choice Pharmacy in the next paragraph, you make reference to a pharmacy known as CVS No. 3322.

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Do you see that?
A. Yes, sir.
Q. And are you familiar with how busy of a store CVS 3322 is?
A. I am not.
Q. Do you know where it is?
A. It's not stated in my report, but I believe it was probably on one of the documents I reviewed.
Q. A store that fills between 500 and 750 scripts per day of all types of medication, is that a busy store?
A. Yes, sir, that's a busy store.
Q. Did you review any documents that showed the ratio of controlled substances to noncontrolled substances at CVS 3322?
A. So unless you have the due diligence file, I'd like to pull mine out.
Q. Happy to show it to you, sir.
A. Okay.
Q. What's a normal ratio of controlled substances to noncontrolled substances?
A. Kind of changed over a period

of time. Now, today, I think there's an expectation that a usual or normal pattern might be somewhere around 20 to 25% controlleds versus noncontrolleds. Back ten years ago, it would have been a much lower, 12, 15%.

Q. Are you familiar with the fact that other DEA employees have testified that 20% is the appropriate percentage and have not -- and haven't changed it over time like you just did?

A. I don't recall reading any of those depositions. My answer to you would be based on my experience as in the cases and the reviews of records that I've reviewed in regards to those statements by registrants.

(Whereupon, Deposition Exhibit Rafalski-18, 7/17/12 Rausch Memo w/Attachment(s), CAH_MDL2804_00000204 - CAH_MDL2804_00000219, was marked for identification.)

BY MR. PYSER:

Q. I'm showing you what's been marked as Exhibit 18. This is the due

diligence file from the CVS 3322 that you reference in your report. And it's in Parma, Ohio, correct?

A. Yes, sir.

Q. And it's got a series of reports of investigation by Cardinal Health, surveillance reports. Do you see those?

A. Yes, sir.

Q. And on Bates page ending 209, it gives the address of the store at 2007 Brookpark Road in Parma, Ohio.

A. Yes, sir.

Q. Do you know how close that is to St. Vincent's Hospital?

A. No, sir.

Q. How about MetroHealth Medical Center?

A. No, sir.

Q. And take another turn of the page to Bates page ending 211.

A. Yes, sir.

Q. Okay. And here, Cardinal Health writes that the percentage of controlled from this store is 18.4%, correct?

A. That's what this document says,

yes, sir.

Q. You don't have any reason to believe this document is inaccurate, do you?

A. Well, my --

MR. PYSER: Counsel, why did you just raise your hand in the middle of his answer? He's free to answer the question.

MR. FULLER: Oh, because I wanted to answer. Sorry.

THE WITNESS: I thought he was going to object. I apologize.

A. So when I see this document, what I would expect is to see some document that would corroborate this information. And I don't think in my experience of doing cases that you would just accept that document on face value.

I would have -- I would have liked to have seen a confirmation document, a utilization or a dispensing report and some calculations to confirm that these are accurate statements.

BY MR. PYSER:

Q. Sir, the memo that we're

looking at at Bates page 211 states that the purpose of this memorandum is to outline the findings derived from the data provided by CVS, and then it goes on to say the data was based on store-specific averages.

Isn't it reasonable to say that Mr. Cameron, who prepared this document, did actually look at that data? Isn't that what he's saying he did there?

A. Well, it says data provided by CVS, but it doesn't say what type of data. It could have been a -- just a list of the same information. I didn't --

Q. So --

A. I would want to see something independent that could verify that.

Q. So you're basing your identification of this store as a store that you believe Cardinal Health failed to report to DEA as suspicious over the fact that you don't have the actual data breakdown in the due diligence file even though there's a memo explaining what the data shows, correct?

MR. FULLER: Object to form.

A. Well, I only see that -- the

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information provided here. In my report, the concern was a change from a large increase of controlled substances, and I would expect to see some kind of explanation for that increase.
BY MR. PYSER:
Q. Well, the monthly script volume is 16,778, and the percentage of controlled remains below 20%, correct?
A. Yes, but -- but the time frame on this is in November of 2013. The increase occurs in October of 2012. I would expect to see some kind of information relative to that specific increase.
Q. You also see the percentage of controlled paid by cash at 2.5%?
Do you see that?
A. Yes, sir.
Q. And that's actually lower than the percentage of noncontrolled paid by cash, correct?
A. Yes, sir.
Q. So there's nothing suspicious about that, correct?
A. Again, I'll make the same kind

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of assessment that I did earlier. I acknowledge that that is what this says, but I might like to see some kind of other verification that these are accurate.
And I make that statement based on my experience with some cases I worked where these type of figures were provided or listed in due diligence but when actually looking at the dispensing reports, that these weren't accurate assessments.
Q. Do you know whether Mr. Cameron did look at the dispensing reports?
A. I do not know if he did or did not look at them.
Q. Do you have any reason to believe that these numbers listed in this document at Bates page 211 of Exhibit 18 are inaccurate? This particular document.
A. I'm not going to accept them to accurate because I don't see anything that would be used to verify the accuracy of them.
Q. And that's the basis for your criticism, is that the due diligence files don't have all of the information that you believe is appropriate, correct?

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A. It's not just what I believe is appropriate; it's what I've learned through my training, guidance, distributor briefings, what requirements are required for making these assessments.
I think the Masters decision speaks to that too, in regards to verifying information during due diligence investigations.
Q. The Masters decision came out in 2017, correct?
A. Yes, but that didn't mean --
Q. Sir, that was a simple question. I asked for the year. I'm going to ask you to stop opining beyond the question.
MR. FULLER: He can provide the explanation he wants to provide.
MR. PYSER: He's going well beyond the question. Yes, we have.
MR. FULLER: We have this time in deposition, and your witnesses did it and I let them complete their answers. You're going to let Mr. Rafalski complete his answers.

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MR. PYSER: It's a simple question.
BY MR. PYSER:
Q. What year --
MR. FULLER: He can --
BY MR. PYSER:
Q. -- did the Masters decision come out?
MR. FULLER: He can complete his answers.
Go ahead, Mr. Rafalski.
A. Do you want me to answer that question or the question prior?
BY MR. PYSER:
Q. Sir, what year did the Masters decision come out?
A. 2017.
Q. Thank you, sir.
Your report also talks about a CVS Pharmacy No. 219 in Florida, correct?
We're going to be on pages 62 and 63 now, 63 in particular.
A. Yes, sir.
Q. Are you aware of the fact that Cardinal Health asked the DEA to investigate

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CVS Pharmacy 219 in Florida? Did you consider that in your report?
A. No, I did not. It doesn't appear in my report.
Q. When DEA investigates a pharmacy, do they have the ability to look at the scripts that were filled by that pharmacy, which would include patient and doctor information?
A. Yes, sir.
Q. When a distributor goes to a customer, to a pharmacy, are they allowed to see the patient information, such as the name of the patient, the doctor, the medical condition for which something might have been prescribed?
A. Well, let me just correct my previous statement. I'm not sure that if I went into a pharmacy and reviewed prescriptions I'd see the medical condition. Sometimes there might be a notation. So I want to correct that answer.
In regards to my answer to the CVS is they could ask for that information. They don't -- I'm not sure they have a

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right -- well, they don't have a right to just go in and ask for it. But they could ask CVS to fashion a prescribing report. I've -- I've obtained them in my experience over the years, and minus the patient information, they could get the same kind of information to lead them to make some due diligence decisions in regards to the pharmacy.
Q. Sir, are distributors allowed to see patient information that's protected from disclosure by the HIPAA laws?
A. No. But it would be easy for them to request a report and not have that information appear.
Q. On pages -- so let's return to that.
So the report that the distributor could ask for from a pharmacy would have less information on it than the report that DEA would have, correct?
MR. FULLER: Form.
MR. PYSER: I'll rephrase in response to --
THE WITNESS: No, I can answer

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that question.
MR. PYSER: Let me rephrase because your counsel made an objection.
BY MR. PYSER:
Q. Are DEA investigators able to ask for information that's not available to a distributor when they want to look at a customer?
MR. FULLER: Same objection.
A. So just the mere ability to go in and look at prescriptions that contain patient information, I would answer yes to that question.
BY MR. PYSER:
Q. On pages 64 and 65 you list out five pharmacies in a chart.
A. Yes, sir.
Q. Have you visited any of those pharmacies?
A. I have not.
Q. Do you know whether or not those pharmacies are active today with active DEA licenses?
A. I do not, and I would not have

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the ability to confirm that.
Q. Really? Have you ever heard of Google?
A. Yeah, but a Google is not going to give me the DEA registration of those pharmacies. It might list the pharmacy and the name, but that would be an assumption it would have the same DEA number.
Q. Is there anyplace where you could go to find out whether a DEA license is still active or not?
A. I think there's a service you can subscribe and pay to that you can do that, but I don't pay for that service.
Q. Okay. You haven't done that for this case?
A. I have not.
Q. Earlier today you mentioned a long-term care -- pharmacies that supply to long-term care facilities, correct?
A. Yes, sir.
Q. Just in simple laymen's terms, what is a long-term care facility?
A. That's usually an in-house -- not a hospital, but it could be like a

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long-term care, assisting living center, incapacitated people, senior people, people unable to fully care for themselves.
Q. Could it also include hospice care?
MR. FULLER: Form.
A. That typically wouldn't be referred to as a long-term care facility because hospice is not long-term care.
BY MR. PYSER:
Q. Do long-term care facilities typically have higher distributions of controlled substances than your average retail pharmacy?
MR. FULLER: Form.
BY MR. PYSER:
Q. In your experience?
A. I can't comment one way or the other on that because in my experience there's small to very large. So it's possible for me to answer either way on that.
Q. On kind of a percentage of controlled substances versus noncontrolleds, do long-term care facilities have a higher percentage of controlleds than an average

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retail pharmacy, generally?
A. I would say lower, general statement.
Q. But there may be exceptions to that?
A. Sure, there's always the possibility of an exception.
Q. Are distributors allowed to change their policies over time?
A. Yes, they are. In fact, I would expect it, as the industry changes and their operations could potentially change.
Q. So if you're looking to compare whether a distributor followed its own policies, it would be important to make sure that the policies you're looking at are from the right time period, correct?
A. Yes, sir.
Q. On page 67 of your report, you discuss 147 suspicious orders for Summit and Cuyahoga Counties from January 1st, 2013 to present. That's in the last paragraph on page 67.
A. Yes, sir.
Q. Now, in reaching that, you note

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that -- or you claim that Cardinal continued to ship the same base codes to many of those customers.
Do you see that?
A. Yes.
Q. In reaching that opinion, you assume that every customer had an accrual cycle that ends on the 21st of the month?
Do you remember that work?
A. I did state that, and I believe I gained that information through a review of one of the depositions.
Q. So it's your belief that the 21st is the dividing line for Cardinal Health, correct?
A. No, sir. I believe that Cardinal Health had, I think, three different dividing lines so that all of the reports -- I believe the statement was so that all of the resets didn't occur at the same time. So I think the 21st was the one in the deposition I reviewed for that particular facility.
Q. That facility being the Wheeling facility?

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A. Yes, sir.
Q. And that's the basis for your claim here?
A. Yes.
Q. Okay. You also note that in the 2012 through '15 time frame, a Cardinal Health employee testified that Cardinal Health failed to report to the DEA approximately 14,000 orders it flagged as suspicious across the country.
Do you see that?
A. What page are you on, please?
Q. Fair question.
Well, do you remember making a -- drawing a conclusion that Cardinal Health -- here we go -- page 68, last paragraph.
Also during the 2012 through '15 time frame, Cardinal's employee testified that Cardinal failed to report to the DEA approximately 14,000 separate suspicious orders.
Do you see that?
A. Yes.
Q. Did you review the letter that

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Cardinal Health provided to the DEA informing them of this issue?
A. I do recall reviewing some documentation on that.
Q. So you're aware that not a single one of those orders actually shipped?
A. It was my impression from reviewing the documents that they had shipped and they found out of their failure to monitor and post distribution.
Q. So it's your belief that some or all of those 14,000 suspicious orders did ship on page 68?
A. Hold on one second, please.
(Document review.)
A. I'd like to review the deposition with the pages, and I didn't bring the depositions, just the other records.
BY MR. PYSER:
Q. Well, you don't cite in your report to the letter that Cardinal Health provided to DEA informing them of this issue, do you?
A. I do not. I cite the deposition testimony.

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Q. And you also don't cite to Cardinal Health's 30(b)(6) response that also explained that not a single one of those 14,000 orders shipped?
A. I don't recall ever reading that. I just recall the testimony in the deposition.
Q. So you never read the Cardinal Health testimony on behalf of --
A. I'm not saying --
Q. -- their 30(b)(6) corporate representative on this, correct?
A. I'm not saying I didn't read it. I don't recall that statement.
Q. Okay. And you don't cite it in the report?
MR. FULLER: I'm sorry, I just want to clarify. You said read the deposition testimony. Ms. Norris didn't testify about 14,000 orders. I think a written response was included that may have addressed that.
BY MR. PYSER:
Q. You never read Cardinal Health's written response that not a single

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one of those 14,000 suspicious orders shipped?
A. I don't have a recollection of reading that document, no, sir.
Q. And do you know how many of those 14,000 unshipped suspicious orders were for customers in Cuyahoga or Summit County?
A. No, sir. I don't think there was information provided that I could make that determination.
Q. So counsel never told you that there were only four unreported unshipped suspicious orders for customers in Cuyahoga and Summit County? They never provided you that information?
A. Well, I don't know that it would have or not been provided to me. I don't recall reviewing it myself, no, sir.
MR. PYSER: Okay. In deference to my colleagues, I'm going to stop here. I'm not going to ask any more questions. We did not have time to get through all the questions I had for you. Your opinion covers 13 separate defendants; therefore, I reserve my right to come back and ask you additional

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questions at a later point in time.
THE WITNESS: Thank you, sir.
THE VIDEOGRAPHER: Going off the record, 4:46 p.m.
(Recess taken, 4:46 p.m. to 4:49 p.m.)
THE VIDEOGRAPHER: We're back on the record at 4:49 p.m.
EXAMINATION
BY MR. EPPICH:
Q. Good evening, Mr. Rafalski. My name is Chris Eppich. I represent the McKesson defendant in this litigation.
A. Good evening.
Q. Thanks for being here today.
Mr. Rafalski, you joined the DEA in 2004, correct?
A. Yes, sir.
Q. Do you have any personal knowledge about McKesson's suspicious order monitoring program from before 2004?
A. No, I have no information or knowledge prior to that date.
Q. Did you attend the distributor briefing given to McKesson?

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A. No, sir, I did not.
Q. Now, you didn't attend DEA's distributor briefing training until 2008, correct?
A. That's correct.
Q. Did you have any personal involvement with McKesson's suspicious order monitoring programs before 2008?
A. No, sir.
Q. What personal knowledge do you have about Mister -- about McKesson's suspicious order monitoring program between 2004 and 2007?
MR. FULLER: Counsel, when you say personal knowledge, you mean from outside the scope of this litigation?
MR. EPPICH: I'm talking about his personal knowledge, his own personal knowledge.
MR. FULLER: Object to the form. Anything that you acquired in the scope of work or internal communications, your Touhy authorization doesn't allow you to discuss, unless it's public

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information.
A. I have no knowledge.
BY MR. EPPICH:
Q. Have you ever visited a McKesson distribution center?
A. Yes, sir.
Q. When was the first time you visited a McKesson distribution center?
A. I've only been there once.
Q. When was that, sir?
A. I believe it was in early 2014.
Q. As a diversion investigator have you ever conducted an audit or cyclic investigation of a McKesson distribution center?
A. No, sir.
Q. Have you ever interviewed persons in McKesson's regulatory affairs department?
A. No, sir. Well, can I maybe make an explanation for that? So when I was on-site, I had discussions with the regulatory affairs person, so I don't know if that would be considered questioning them.
Q. Did you -- pardon me.

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A. But I had some discussion. I don't want to think that -- make sure I have a complete answer that --
Q. Did you discuss McKesson's suspicious order monitoring program during that visit?
A. I think there was some broad discussion about it.
Q. And when would that have occurred?
A. 2014.
Q. So at least for the time period between 2004 and -- or pardon me, strike that.
The opinions that you express in your report for McKesson's suspicious order monitoring program from 1997 to 2007, those opinions are based only on the documents and the portions of deposition transcripts that you reviewed as identified in Appendix I to your report?
A. Yes, sir.
Q. Let's go ahead and turn to page 70 of your report, sir. Are you on page 70?

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A. I am, sir.
Q. I noticed that your report has page numbers on it. The report produced to us does not have page numbers. When did you last update your report, sir?
A. Yeah, I'm aware that you probably have one that does have page numbers, but it has page 1.
Q. Yes, sir. They're page 1 all the way down sequentially throughout the report.
MR. FULLER: So every page is page 1.
A. So when I submitted my report, the explanation that I received, because my original one came back as page 1, is that there was some kind of a conversion to a PDF or something that was done in order to submit it to the court, and that's what caused the pages to change.
So subsequent to that, I asked to have one with the page numbers.
BY MR. EPPICH:
Q. And other than the update of the page numbers to the proper page numbers,

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are there any other changes between the report that you have in front of you and the report that was produced in this litigation?
A. No, sir, I made no changes.
MR. EPPICH: I'm going to go ahead and mark as Exhibit 15 the report that was produced in this litigation to counsel.
(Whereupon, Deposition Exhibit Rafalski-15, Rafalski Expert Report, was marked for identification.)
MR. EPPICH: I'll hand you a copy of that and you can set it aside.
BY MR. EPPICH:
Q. And simply because we don't have a copy of that report that's in front of you, let's go ahead and mark your binder as Exhibit 17. And we can just mark the outside of the binder -- pardon me, Exhibit 16. And we'll go ahead and give this to the court reporter at the end for copying.
Thank you so much.
A. Sure.
(Whereupon, Deposition Exhibit Rafalski-16, Witness' Copy of Rafalski

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Expert Report, was marked for identification.)
BY MR. EPPICH:
Q. All right. Back to page 70. Now, Section 2 of page 70 -- this is in the McKesson-specific section -- is titled SOMS Corporate Policy Disclosed.
Do you see that heading?
A. I do, sir.
Q. And here you discuss McKesson's so-called excessive purchase reports described in McKesson Drug Operations Manual, Section 55, correct?
A. Yes, sir.
Q. You state -- and this is about halfway down that paragraph, sir: McKesson created daily and monthly reports that documented retrospective sales of controlled substances, including opioids, when those sales exceeded three times of that customer's 12-month purchase average for that base code.
Did I read that correctly?
A. You did.
Q. Now, this -- this suspicious order monitoring system that's described

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here, what we call the Section 55 program, you're aware that this program, the McKesson Section 55 program, operated in a similar way to ABDC's program that we heard about earlier?
A. I'm not sure I would agree with that statement. McKesson generated five different reports, although the only report that -- well, I referenced the five different reports, but the DU-45 was the report that was generated and sent to the DEA post distribution.
Q. And the DU-45 is what has been called a so-called excessive purchase report, correct?
A. That or ingredient limit report, those are two names that they have been referred to, yes, sir.
Q. Both McKesson and ABDC's systems, they used a multiplier of the customer's prior monthly purchase averages to detect suspicious orders, correct?
A. They did use a multiplier. I'm not acknowledging that I accept that, the use of that multiplier, but they do use a

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multiplier.
Q. They both use a multiplier.
And both McKesson and ABDC's systems, they report suspicious orders on a daily or monthly basis after the order has been shipped.
That was part of the old program, right?
A. Well, based on that algorithm, they were reporting -- making reports on a monthly basis to the DEA, yes, sir.
Q. And it's really no surprise that McKesson's Section 55 program is similar to ABDC's program that we discussed earlier, is it?
A. I have no comment on that, that it would be similar. There are some programs that are very similar and maybe there's some affiliation and then there's others that are completely different. So I don't know that it's by coincidence or if it's structured that way.
Q. Well, distributors were all receiving guidance from DEA at the same time during presentations and conferences, right?

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A. Well, that was one of the sources of some of the decisions. I also -- my experience says they belong to HDMA, NWDA. I went over -- had various names over various time periods. They were also receiving guidance, I believe, or conducting meetings with them where they were maybe collaborating or sharing information.

Q. So if McKesson's Section 55 program had been out of compliance with federal regulations and DEA was conducting audits of the McKesson facilities, wouldn't DEA have told McKesson during its annual audits that its program was out of compliance?

A. I would have an expectation that if a person was to go on site and actually review the system, that I would have an expectation that there -- maybe should make some comment or do some corrective action.

Now, I don't know if an on-site visit, they actually reviewed it and secondly, even if they went on-site and missed it or did review it and issued or made

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some corrective action, that doesn't mitigate the responsibilities of the registrant.

Q. And that's fair, but it's one of the purposes of this audit for DEA to go to the facility of the distributor to review the SOM system and to provide feedback, correction -- corrective feedback to the distributor, if corrective feedback is needed?

A. So can I describe a little bit further what an on-site visit is? It's not a checklist type of a visit. It's a three-pronged investigation: security, recordkeeping and accountability. Every DEA investigator conducts it in whatever manner they see fit as long as they cover those three areas or prongs of activity.

So it's -- there's nothing in the DEA's requirement that they would specifically have to look at that or take action, although I would say my expectation is they should.

Q. Now, you were a DEA diversion investigator between 2004 and 2017, correct?

A. Yes, sir.

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Q. And between 2004 and 2007, you testified that you didn't visit a McKesson facility?

A. Yes, sir.

Q. Are you aware of any DEA personnel that told McKesson between -- between 1997 and 2007 that its Section 55 program was violating the CSA and its regulations?

A. I'm not aware that anyone ever told them, made that statement to McKesson.

Q. Now, McKesson operated a distribution center here in Detroit during this time, right?

A. Livonia, Michigan, I believe.

Q. Yes, sir. And in not telling McKesson that the DEA believed its system was violating the CSA, was the DEA contributing to the cause of the opioid crisis?

A. I don't really have an opinion on that one way or the other. I just want to go back and reaffirm my earlier statement is what the DEA did or didn't do, that didn't diminish or take away the regulatory and legal -- the law requirements for what

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McKesson should have done.

Q. But you have no opinion sitting here today as to whether or not the DEA's failure to tell distributors whether or not their compliance programs violated the CSA contributed to the opioid crisis; is that correct?

A. That's an accurate statement, yes, sir.

Q. And why haven't you formed that opinion?

A. Well, because the corporations or the companies that distribute drugs, their responsibility is clearly stated in the law and within the regulations. If the DEA was to come out and make an error, that doesn't mitigate their needs to make compliance.

So -- and along the way, there's -- a lot of times where McKesson gets guidance through industry conferences, I think you stated, distributor briefings, they have the ability to write or ask questions to the policy section of the DEA.

So just for clarification, I don't know if anyone ever reviewed or

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commented on that system, and it doesn't diminish their responsibility under the law and under the regulations.
Q. But you agree that DEA is the agency in the federal government that has authority and responsibility for the controlled system of drug distribution in this country, correct?
A. In -- yes, sir. In regards to the regulation, they're delegated that by the Attorney General, by Congress to the Attorney General, so I agree with that statement, yes, sir.
Q. Let me --
A. And let me just clarify.
MR. FULLER: Go ahead, finish.
MR. EPPICH: I'm really on a limited amount of time here, sir.
MR. FULLER: But you can finish and clarify your answer.
A. Just a quick clarification. I don't want to misstate. I believe anybody who had anything to be involved with the distribution of controlled substances during this whole time period should have taken

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positive steps to prevent diversion. I don't want you to think that I don't believe that no one had that responsibility.
BY MR. EPPICH:
Q. And that would include the DEA, correct?
A. Everyone.
Q. Is that a yes, sir?
A. Yes, sir.
Q. And I'd like to go back to our discussion earlier about the do not ship requirements. You're familiar with 21 CFR 1301.74(b), correct?
A. I am, sir.
Q. And that's the one -- that's the one -- that's the -- strike that.
This is the regulation that you call the security requirement, correct?
A. I don't call it a security requirement. It falls under the security requirements of the CFR.
Q. What are the security requirements of the CFR then, if you could list them for us?
A. Well, I'd need a CFR. I

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don't -- a corporate relations --
Q. Is there anything beyond Section 1301.74(b)?
A. Well, there's many. There's a security requirement just prior to that where it requires a registrant to make a good faith -- a good-faith inquiry before distributing a controlled substance to ensure that the person has a -- as a registrant has a valid DEA registration.
There's extensive amount of regulations in regards to security of cages and vaults, very detailed. The type of gauge of wire, the distance of the posts, ceilings, self-closing doors. There's vault requirements, the rebar.
It's a whole extensive list of security requirements and the security -- the suspicious order systems within that section.
Q. So on page 9 of your report, if you could turn there, we're in Section B under Regulatory Duty?
A. Yes, sir.
Q. It says: The "security requirement" at the heart of this case

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mandates the distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA, quote, the Reporting Requirement, 21 CFR 1301.74(b).
In this paragraph, is the security requirement that you're talking about, is that Section 1301.74(b)?
A. Yes.
Q. Okay. So in the security requirement, my question for you is: Where in the security department does it state the do not ship requirement?
MR. FULLER: Form.
A. So the overarching right to regulation that's directly controlling this is the maintenance of effective controls to prevent diversion. It would be within that regulation which the do not ship decision -- or the do not ship requirement would fall.
BY MR. EPPICH:
Q. But you agree with me that the security requirement itself does not say the words "do not ship," does it?
A. The security requirements do

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not say those specific three words.
Q. And the security requirement does not say "block orders," does it?
A. It doesn't -- the security requirement doesn't specifically say that, but as I stated earlier, those are contained within the maintenance of effective controls to prevent diversion.
Q. And my question, sir, was just that the words are not used.
A. Okay.
Q. Okay. If we could turn back to page 40 of your report.
A. I'm sorry, what page?
Q. 40. I'd like to turn to our discussion of the five methodologies that Dr. McCann used in his analysis. And you mentioned earlier today that you came up with the idea to use those five methodologies, correct?
A. Yes, sir.
Q. And when did you come up with each of the five methodologies?
A. I don't have a specific data. I know that I was told that I would have to

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come up with five methodologies, so I elected to use the five that I was aware of in conducting this review for my opinion.
Q. Who told you to come up with the five methodologies?
A. I believe my first conversation about this was with Paul Farrell.
Q. And do you recall when that first conversation was?
A. I do not.
Q. Was it last summer?
A. No, it was a little later than last summer.
Q. Later than last summer.
Did you communicate with any attorneys other than Paul Farrell in coming up with these five methodologies?
A. I'm not drawing any direct recollection, but I'm hesitant to just say no because I've talked about this matter, and I would probably say it's more likely than not that I had some conversation about my methodology.
Q. And did you have any written conversations or communications about these

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methodologies with plaintiffs' counsel?
A. I don't believe so, telephone conversations.
Q. Now, of the five methodologies, do you know which of these methodologies was used by McKesson, if any?
A. The 8,000 -- D, the methodology with the maximum 8,000 dosage units monthly.
Q. Any others?
A. I think the -- if I remember correctly, the three times.
Q. Now, the three times -- that's the third methodology -- do you know when McKesson in your opinion used that methodology?
A. No, but I can review my report if you'd like me to.
Q. I don't believe it says it in there.
A. Okay. Mind if I look?
Q. No, I do mind.
Do you know when McKesson used --
MR. FULLER: Go ahead and take a look.

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MR. EPPICH: I'll strike the question.
BY MR. EPPICH:
Q. Do you know when McKesson used the 8,000 dosage unit methodology?
A. May of 2007 as part of their Lifestyle Drug Monitoring Program.
Q. For about a year; is that correct?
A. Yes, sir.
Q. Now, you call this use of the 8,000 dosage units the McKesson Rule, do you not?
A. I don't believe I refer to that in my report as the McKesson Rule.
Q. Have you heard of that slogan, the McKesson Rule?
A. No, I have not.
Q. Earlier today I believe you mentioned that you saw some positive things from McKesson's suspicious order monitoring programs.
Do you remember that testimony?
A. Yes, sir.
Q. What positive things did you

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see in McKesson's suspicious order monitoring program?
A. At the very end of the time period, they contracted or -- a company called AGI, and AGI did a -- was designing a model for them, and I thought just by looking what limited information I got, that I thought there was some potential for that.
I'm not saying that I'm approving it, and without actually doing a lot more analysis, but I thought that that was -- had the potential for a good system.
Q. As you sit here today, do you have any opinions on whether McKesson's AGI suspicious order monitoring program complies with the CSA and its regulations?
A. No, I did not evaluate it because it was at the end of the time frame.
Q. Do you have any plans to make that evaluation before trial?
A. If required or requested.
Q. Has anyone requested that you do so today?
A. No, sir.
Q. So currently, as you sit here

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today, you have no opinion about whether or not McKesson's AGI suspicious order monitoring program complies with or does not comply with the CSA, correct?
A. I did not offer opinion on that matter, sir.
Q. You testified earlier about ARCOS. Are you familiar with the reports generated from the ARCOS database?
A. What type of reports are you speaking of, sir? Could you clarify?
Q. The reports that a diversion investigator can request from the ARCOS database?
A. Oh, so generated pursuant to a request? Yes, sir.
Q. Okay. And you saw those kind of reports while you were a DEA diversion investigator, correct?
A. I requested those type of reports as a diversion investigator.
Q. On page 15 of your report --
A. 15?
Q. 15.
You discuss ARCOS, and in the

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third paragraph from the top of the page, you say: The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typical rely on in conducting the analysis and reaching the opinions contained therein.
Do you see that?
A. I do, sir.
Q. Now, is it your opinion that Dr. McCann's five threshold-based methodologies can be used to identify suspicious orders under Section 1301.74?
MR. FULLER: Form, compound.
A. You're asking this question about Dr. McCann in regards to this paragraph?
BY MR. EPPICH:
Q. I can rephrase it.
Is it your opinion that the five threshold-based methodologies used by Dr. McCann and cited by yourself, that those methodologies can be used to identify suspicious orders under Section 1301.74?
A. No, I think my opinion is clear

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that they aren't suitable suspicious order systems.
Q. Is it your opinion that Dr. McCann's -- and I quote -- "flagged orders" are suspicious orders under Section 1301.74(b)?
A. Are you jumping back to the methodologies?
Q. I'm just asking you a question, sir.
MR. FULLER: You can clarify the question if you don't understand.
BY MR. EPPICH:
Q. But, yes, under the methodologies. Under the methodologies, yes, sir.
A. No, those aren't suspicious orders under the methodologies. Those are dosage units.
Q. While you were at the DEA, and the DEA was analyzing ARCOS data, did DEA use any of Dr. McCann's five methodologies to identify suspicious orders?
A. When I was at the DEA?
Q. Yes, sir.

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A. I was gone from the DEA prior to Dr. McCann looking at that data. I guess I don't understand the question.
Q. While you were at the DEA, did the DEA analyze ARCOS data using the methodologies that Dr. McCann presented and you also presented in your report?
A. No, sir.
DEFENSE COUNSEL: We understand the phone line has been disconnected.
MR. EPPICH: Let's go off the record.
THE VIDEOGRAPHER: Going off record at 5:13 p.m.
(Recess taken, 5:13 p.m. to 5:18 p.m.)
THE VIDEOGRAPHER: We're back on the record at 5:18 p.m.
BY MR. EPPICH:
Q. Mr. Rafalski, before the break, we were talking about Mr. McCann's analysis on page 40 of your report. If you could turn there.
A. Sure.
Q. Earlier today -- let me strike

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that.
You're aware that Dr. McCann's results rest on the assumption the distributors did not conduct any diligence on the first flagged suspicious order, correct?
A. Yes, sir.
Q. Is it your opinion that McKesson did not conduct any diligence of any customer ever identified in its suspicious order reports?
A. I'm going to just confirm my statement on that, whether it was sufficient or no.
(Document review.)
A. In reviewing my report, my report states and my recollection is, is there was no due diligence conducted between the time period of '97 and 2007, at least no evidence indicating that or records indicating that.
And then in the time periods following that, there was insufficient due diligence. There was level one due diligence, but there was no subsequent level two and level three, and the level of due

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diligence was insufficient.
BY MR. EPPICH:
Q. And your opinions are based on your review of McKesson's documents that were produced in this case, correct?
A. Yes, sir.
Q. You have no personal knowledge about whether or not McKesson did any due diligence before at least 2014 when you visited their -- the McKesson distribution center, correct?
A. Say that question one more time. I'm sorry.
Q. I'm going to strike the question.
Now, you -- it's true that McKesson may have discarded diligence files, correct?
MR. FULLER: Object to form, speculation.
A. Just so I understand, it's true that they may have discarded due diligence files?
BY MR. EPPICH:
Q. Yes.

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A. I don't know that to be a factually accurate statement.
Q. Well, it's possible that McKesson may have discarded diligence files, correct?
MR. FULLER: Form.
A. All I make comment on is whether or not they were provided to me. I have no way to know if there was any explanation outside of that.
BY MR. EPPICH:
Q. Your opinions are based solely on the documents that were provided to you in this litigation, correct?
A. Or the lack of documents or the content of the documents, yes, sir.
Q. And you have no personal knowledge about McKesson's due diligence, correct?
A. No, sir.
Q. What is your personal knowledge?
A. I have no personal knowledge.
Q. Thank you.
A. That's what I was saying no,

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sir, to.
Q. So if McKesson did conduct due diligence on the first flagged suspicious order under its Section 55 program, you'd agree that Dr. McCann's analysis is based on a faulty assumption, correct?
MR. FULLER: Form.
A. Well, I'm not sure it's a faulty assumption. I guess it would be the level and whether it was sufficient due diligence. Just conducting a due diligence investigation doesn't itself meet the requirements of maintenance of effective controls, so -- and I think my statement is the review of the level ones were insufficient due diligence.
BY MR. EPPICH:
Q. And the level of sufficiency of the due diligence is based on your review of McKesson documents alone, correct?
A. Yes, and my experience in -- as a DEA investigator of due diligence files.
Q. And what is sufficient due diligence in your mind?
A. Well, I think it has to be a

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sufficient investigation to remove any suspicion that the drugs could be potentially diverted and if they're intended for a legitimate source, a legitimate use. So it would be those actions that they would take to be able to confirm that and document it so I would be able to review it.
Q. And what is sufficient?
A. Well, to merely say increase in volume would not be sufficient due diligence. I think every circumstance is a little bit different, so I guess I would have to look at the records.
I don't know that I could say that there's a check -- I could provide a checklist, but I don't know if that would be sufficient, because it's dependent on the scope of the business and what their needs are and what's been established as usual or what's normal.
Q. So if McKesson conducted sufficient due diligence on the first flagged suspicious order under its Section 55 program, you'd agree that Dr. McCann's analysis is based on a faulty assumption?

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MR. FULLER: Form.
A. Well, if that did occur, then the analysis would stop and it would start again from that point forward.
BY MR. EPPICH:
Q. You'd agree that at least Dr. McCann's results would change in that circumstance?
A. Yes, I would agree with that.
Q. And you'd agree that if McKesson conducted sufficient due diligence on the first flagged suspicious order under its LDMP program, that McKesson's results would change, correct?
A. I want to clarify my answer on the last one.
So I would suspect that in the course of all of the suspicious orders, that maybe there could be one due diligence file. But I think until there would actually be a consistent review of orders -- so -- and I know that probably needs a little clarification.
Just say that one employee became very interested and did a thorough due

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diligence, but that wasn't the program, and it was just one occurrence, then I don't think it's really faulty.
I think it requires that the company acted -- actually had to have some procedure in place to actually do due diligence investigations, not just one instance.
Q. But in your report you assume that there was no due diligence and that Dr. McCann then relied on that assumption, correct?
And so my question is very specific: If McKesson conducted sufficient due diligence on that first flagged order under its LDMP program, its CSMP program, its Section 55 program, you would agree sitting here today that the results that we see from Dr. McCann's analysis, they would be different?
MR. FULLER: Object to form, misstates the fact. The witness didn't make the assumption there was no due diligence. He's testified based on his opinion there's not

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adequate due diligence.
A. That's hypothetical. I wouldn't say one -- one due diligence would reset it if the company's conduct continued along the same, the same level, so -- and my -- and my requirement to Dr. McCann was that during the entire time period, I did not see a sufficient due diligence to satisfy the regulatory requirements, so that's why it was ran during the whole time frame.
BY MR. EPPICH:
Q. How many due diligence investigations or analyses would be enough to be sufficient due diligence?
A. Every one of the suspicious orders.
Q. Did you review any of the flagged orders from Dr. McCann's analysis of McKesson?
A. No, sir.
Q. Do you intend to offer any opinions on whether the orders flagged by Dr. McCann are legitimate or suspicious?
A. If that requirement is required of me by the attorneys in the case, I would

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complete that analysis. I don't have any independent intentions of doing that.
Q. Sitting here today, you have no opinions about the legitimacy of the flagged orders from Dr. McCann's analysis, correct?
MR. FULLER: That misstates his report.
A. It's -- Dr. McCann's report doesn't report orders, it just reports dosage units. It doesn't say how many orders. It doesn't say there was an analysis of each individual order.
It looked at them whether or not they violated the trigger that was provided for each one of them, and if it -- and then it moved forward without the -- because already knowing that there was insufficient due diligence.
BY MR. EPPICH:
Q. And you reviewed -- let me strike that.
Let's turn to page 74 of your report. On page 74, I'm looking at Section 6, the second paragraph in particular. The first sentence there says:

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There is no more effective control to prevent diversion than blocking a suspicious order before it is shipped.
Did I read that correctly?
A. You did, sir.
Q. And that's because a blocked order of opioids remains safely in the vault of the distributor's warehouse, correct?
A. I guess you could make that assumption. It doesn't leave the control of the distributor and have the potential to be diverted, so I think that's probably the same statement, yes, sir.
Q. You'd agree that reporting the blocked order to DEA in a suspicious order report does not prevent the blocked order from being diverted, correct?
A. Well, that hypothetical wouldn't occur because if you block an order and report it, that doesn't -- unless you're saying that that causes a distribution, and if that causes the distribution without the effective due diligence, then no, that would not be true.
I would say that it would

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probably be more prone to be diverted than not diverted because you've already identified it as a suspicious order.
Q. Would you agree that a suspicious order monitoring program that does not report suspicious orders but blocks suspicious orders can be effective in preventing diversion?
A. It doesn't meet the regulatory requirement.
Q. But can it be effective in preventing diversion?
A. That's a hypothetical I'm not going to comment on.
Q. You don't have any opinion on whether or not a suspicious order monitoring program that does not report suspicious orders but blocks suspicious orders can be effective in preventing diversion?
MR. FULLER: Object to form.
A. I don't really have an opinion because it's -- it wouldn't be something that would be evaluated as regards to the -- to the regulation.
If hypothetically the --

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McKesson decided not to ship any more controlled substances, that would -- you know, there would be no diversion, so it's just a hypothetical that --
BY MR. EPPICH:
Q. Yes, and you're an expert in this case, sir.
A. I don't have an opinion.
Q. So hypothetically, if there is a suspicious order monitoring program --
A. Okay.
Q. -- that reports a suspicious order -- or excuse me, that does not block -- let me strike that.
If there is a suspicious order monitoring program that does not report suspicious orders but blocks suspicious orders, that program can be effective in preventing diversion?
A. So the mere act of doing that is in violation of the regulation, but the outcome of blocking the order would obviously keep it from being distributed and it would not lead to diversion.
Q. Blocking the order of the

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opioid pills before shipment is what prevents diversion from occurring, correct?
A. Yes, sir.
MR. FULLER: Form.
BY MR. EPPICH:
Q. Not the reporting of the suspicious order to DEA, correct?
A. But we were discussing the regulatory requirement, so it's to design and operate a system to disclose suspicious orders, and upon disclosure, be reported to the DEA. Under the maintenance of effective controls, it's to stop the shipment.
Now, just the mere fact of stopping a shipment when you've identified it as a potential suspicious order would prevent diversion.
Q. My question was a little different, and so let me rephrase it.
You'd agree that not reporting the suspicious order to DEA is not what causes diversion?
A. That's correct.
MR. FULLER: Object to form.
///

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BY MR. EPPICH:
Q. If we could turn to page 78 of your report. You state -- and I'm under Section (a), Policy Period #1. There's a statement about six lines, seven lines down, it says: Multiple McKesson regulatory employees have acknowledged that the DU-45 reports were not meant to detect true suspicious orders.
Do you see that?
A. Yes, sir.
Q. What do you mean by true suspicious orders?
A. Well, true suspicious orders would be based upon a properly designed suspicious order system, and which they would actually be suspicious orders.
If a system is in place that discloses orders to the DEA and the employees believe they're not suspicious, then it wouldn't be a true suspicious order system -- or suspicious order.
Q. So by true suspicious orders, are you referring to suspicious orders according to the definition that we see in

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Section 1301.74(b)?
A. A true suspicious order is, you know, a result of a system that's in place -- an effective system that's in place by a registrant under the guidelines of 1301.74(b).
Q. And so a true suspicious order is one that is an order of unusual size or an order that is of an unusual pattern or of an unusual frequency; is that what you're saying?
A. That's one -- that's three of the general parameters that the DEA -- that's listed in the regulation, but there are other things that could occur that could make it a suspicious order.
Q. Did you write this sentence?
A. Which sentence?
Q. The sentence that we just read: Multiple McKesson regulatory employees have acknowledged that the DU-45 reports were not meant to detect true suspicious orders?
A. Yes, sir.
Q. Did you use the word "true" yourself?

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A. Yes, sir.
Q. If we could turn to page 80. Now, in section -- on page 80 under the section titled Reporting Requirement, you state that McKesson reported less than one-half of 1% of orders from Cuyahoga and Summit Counties.
Do you see that? It's at the very bottom of the paragraph under Reporting Requirement.
A. I'm sorry, what page are you on?
Q. I'm right here on page 80 in Reporting Requirement.
A. Okay.
Q. And I'm looking at the very last -- last line of that -- or second-to-last line.
A. Okay. I'm sorry.
Q. You see where you say that you -- that McKesson reported less than one-half of 1% of orders from Cuyahoga and Summit Counties?
A. Yes, sir.
Q. Now, you go on to claim that

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using any of the methodologies as described in the expert report of Craig McCann, it is apparent McKesson failed to report thousands of suspicious orders arising out of Cuyahoga County and Summit County.
A. Yes, sir.
Q. Do you see that?
A. Yes, sir.
Q. Now, your opinion that McKesson failed to report thousands of suspicious orders is entirely dependent on Dr. McCann's analysis, correct?
MR. FULLER: Form.
A. You have to repeat that question. I'm sorry.
BY MR. EPPICH:
Q. Yes. No problem. Let me clarify it.
Is your opinion that's expressed on page 80 and that I just mentioned, that McKesson failed to report thousands of suspicious orders arising out of Cuyahoga County and Summit County -- is that opinion based entirely on Dr. McCann's analysis?

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A. I think he did the analysis at my request, as the footnote states from -- yes, if I was to review Section III of my report. So it's not something he did independent.
I guess maybe I don't clearly understand the question.
Q. What is your basis for the opinion -- your opinion that it is apparent McKesson failed to report thousands of suspicious orders arising out of Cuyahoga County and Summit County?
A. Well, first, just based on the first system in place from '97, the DU-45s, and then the subsequent, the 8,000 policy that followed that, the lifestyle, and then the policy that followed there -- followed there that's ineffective.
Q. How did you arrive at the number thousands?
A. Well, that calculation was done by Dr. McCann.
Q. Do you have any other basis for your determination that thousands of suspicious orders were not reported by

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McKesson in these counties?
A. No, other than just my review of the policies and the procedures of McKesson, the lack of due diligence, and their suspicious order systems they had in place.
Q. Let's turn back to page 80, and I'm looking under the Shipping Requirement.
A. Yes, sir.
Q. You say there that McKesson's blocking of 2,907 out of 772,976 opioid orders from Summit and Cuyahoga County customers is minuscule.
Do you see that?
A. Yes, sir.
Q. You also say that those numbers make it apparent that McKesson's system have not been properly designed to block suspicious orders; is that true?
A. Yes, sir.
Q. Let me ask you: How many orders should McKesson's suspicious order monitoring system have blocked in order for you to consider McKesson's system to have been properly designed?

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MR. FULLER: Form.
A. That -- there's no answer to that question because there was no proper system in place, so --
BY MR. EPPICH:
Q. Well, you're saying 2900 is too low.
A. Well, I'm just saying --
Q. So I'm asking how many is the right -- just give me a ballpark.
A. I don't have a ballpark. All I know is by evaluating the system that was in place that McKesson had through the time period of my evaluation, in my opinion, they had an insufficient system, and it's based against the total number of distributions.
Q. So you have no opinion, sitting here today, how many orders McKesson should have blocked during this time period from Summit and Cuyahoga Counties?
A. Every one that they identified with their suspicious order system, which I believe was ineffective, should have been blocked when it was identified.
Q. Do you think 80% of orders

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should have been blocked?
A. I think every order identified by the McKesson system should have been blocked. I don't think that allowing 20% of the orders that are identified as suspicious to flow outside of McKesson's control would have been appropriate action.
Q. How do you know that 20% of McKesson's orders flowed?
A. Based on your previous question. You -- I think you referenced 20% amount, if only 80% were blocked, if that would be sufficient. Unless I misunderstood your question.
Q. We're going to move on. Let's turn to page 15 of your report.
A. 15?
Q. Yes, sir.
Now, on page 15 of your report, sir, under Section E, the DEA Diversion Investigator's Manual?
A. Yes, sir.
Q. Your first sentence says: The DEA published a manual which provides further guidance related to the statutory and

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regulatory duties.
Do you see that?
A. Yes, sir.
Q. The manual you're referring to in that sentence, is that the DEA Diversion Investigator's Manual?
A. Yes, sir.
Q. You agree that the DEA Diversion Investigator's Manual is not available to registrants?
MR. FULLER: Form, misstates the evidence.
A. I believe it was provided to registrants.
BY MR. EPPICH:
Q. So if a registrant asked in 1996 for a copy of DEA's Diversion Investigator's Manual, you as a DEA diversion investigator could hand over that manual; is that what you're saying?
A. I'm not saying that. I'm saying that I have knowledge that in 1996, a DEA registrant asked -- I believe requested it and it was provided to him.
Q. Which registrant?

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A. Cardinal.
Q. Do you have any knowledge of McKesson receiving a DEA Diversion Investigator's Manual?
A. No, sir.
Q. Now, I'd like to look at the quote that you have excerpted on page 15 of your report. You're familiar with that -- with that excerpt, aren't you?
MR. FULLER: I'm sorry, what page, Counsel?
MR. EPPICH: On page 15.
A. The bold section, the italics?
BY MR. EPPICH:
Q. The entire quote, sir.
A. Yes, sir.
Q. Do you know where that quote comes from?
A. The manual.
Q. Which version of the manual, sir?
A. I believe the 1996 manual.
Q. And it's from Section 5126, Requirements to Report Suspicious Orders; is that correct?

MR. FULLER: If you recall. If not, you can pull the document.
A. I don't recall specifically.
BY MR. EPPICH:
Q. Now, the excerpt that you have provided in your report on page 15, this does not say do not ship an order reported to DEA as a suspicious order, does it?
A. Doesn't say the terms "do not ship," if that's your question, no, sir.
Q. Thank you.
MR. EPPICH: Why don't we go off the record for a really quick break.
THE VIDEOGRAPHER: Going off the record at 5:43 p.m.
(Recess taken, 5:43 p.m. to 5:45 p.m.)
THE VIDEOGRAPHER: We're back on the record at 5:45 p.m.
BY MR. EPPICH:
Q. If we could turn to page 10 of your report. On page 10, the first full paragraph at the top of the page says: The regulatory duty not difficult to understand,

as one who voluntarily applies to become a registrant must submit an application and undergo a preregistration investigation. The preregistration investigation involves a thorough on-site inspection of the registrant's facilities as well as extensive discussions of the applicable regulations and the security requirements that must be followed.
Did I read that correctly?
A. Yes, you did.
Q. Now, it's true that each pharmacy, distributor and manufacturer must register with the DEA in order to lawfully handle controlled substances in the closed system of distribution, correct?
A. Yes, sir.
Q. Each pharmacy, distributor and manufacturer must submit an application to DEA?
A. Yes, sir.
Q. The DEA then conducts an on-site inspection of each applicant's facilities, correct?
A. They do not conduct on-site

investigations of pharmacies, at least not in the Detroit division.
Q. Your testimony here today is that they conduct on-site inspections of distributors?
A. Yes, sir, and manufacturers prior to approval of a registration.
Q. Why doesn't the DEA conduct on-site inspections of pharmacies?
MR. FULLER: Object to form, remind you of your Touhy obligation and internal conversations.
THE WITNESS: On advice of my counsel, I'm not going to answer that question.
BY MR. EPPICH:
Q. Does DEA discuss the regulations and security requirements with each pharmacy, distributor and manufacturer applicant before registration?
A. Affirmative to distributors and manufacturers. No with pharmacies.
Q. Why doesn't DEA discuss the regulations and security requirements with pharmacy applicants before registration?

MR. FULLER: Objection and the same Touhy reminder.
THE WITNESS: On advice of counsel, I'm not going to answer that question.
BY MR. EPPICH:
Q. Now, you're familiar with 21 CFR Section 1301.74(a), correct?
A. Yes, sir.
Q. Now, Section 1301.74(a) requires registrants to check the registration status of its customers before distributing a controlled substance to that customer, correct?
A. Yes, I believe it says to make a good-faith effort to check.
Q. And DEA conducts all of this diligence on applicants so the distributors can rely on the DEA registrations when complying with 1301.74(a), correct?
A. I'm sorry, you have to say it one more time.
Q. You'd agree with me that DEA conducts diligence on its applicants so that distributors can rely on the DEA

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registrations when complying with 1301.74(a)?
A. Whether or not they posses a valid DEA registration, is that what you're asking? Yes, sir.
Q. Let me make sure my question was clear. You would agree that DEA conducts diligence, reviews applications, looks at the background of these applicants so that distributors can rely on the DEA registrations when complying with 1301.74(a)?
MR. FULLER: Object to form.
A. So if your question is in regards to pharmacies, they don't conduct those types of investigations, so I'm -- maybe I'm still confused by the question.
BY MR. EPPICH:
Q. My apologies for that.
It's true that distributors are to rely on active DEA registrations when complying with 1301.74(a)?
A. Yes, sir. They are required by regulation to make a good-faith effort to confirm that the person that they're going to distribute drugs to has a valid DEA registration.

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Q. And that's actually the only requirement under Section 1301.74(a), correct?
A. Yes, it is.
MR. EPPICH: Mr. Rafalski, I appreciate your time today. It's been short, and there are a lot of questions that McKesson has for you that we won't be able to get in the brief time I have, so we will reserve our right to return and reopen this deposition if need be. Thank you so much. We're off the record.
THE VIDEOGRAPHER: Going off the record at 5:50 p.m.
(Recess taken, 5:50 p.m. to 5:58 p.m.)
THE VIDEOGRAPHER: Back on the record at 5:58 p.m.
EXAMINATION
BY MR. JONES:
Q. Good afternoon, Mr. Rafalski. My name is Scott Jones. I'm going to ask you some questions for my clients, Henry Schein Inc. and Henry Schein Medical

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Systems Inc.
Do you understand that?
A. Yes, sir, good evening.
Q. Good evening.
You mentioned earlier when you were asked to kind of allot the amount of time that you've spent in looking at the various defendants; and you mentioned Henry Schein earlier.
Do you remember that?
A. Yes, sir.
Q. And you mentioned that you hadn't spent as much time looking at them as the other defendants, correct?
A. In proportion to the larger distributors, yes, sir.
Q. And in your report, you make reference to the CT1 cases?
A. Yes, sir.
Q. And it's the Track 1 cases?
A. (Nods head.)
Q. And what do you understand those cases to be?
A. Distributions into the two counties, Cuyahoga County and the other

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county.
Q. Summit?
A. Yeah, Summit County, thank you.
Q. And you understand that each of those is a separate lawsuit and Henry Schein is only named to one of those lawsuits?
A. Yes, sir.
Q. Do you know which one?
A. I don't recall right off the top of my head, no, sir.
Q. I'll tell you that's the Summit County lawsuit.
A. Okay.
Q. If you would, you've got your report in front of you?
A. Yes, sir.
Q. If you would flip over to page 40 of your report.
A. Back to the methodologies. Okay.
Q. And down there, Roman numeral III, Identifying Suspicious Orders Distributed in CT1.
Do you see that?
A. Yes, sir.

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Q. And then on the next page are these five methodologies, right?
A. Yes, sir.
Q. And listening today, I understand that these are your five methodologies, correct?
A. Yes, sir.
Q. You came up with these?
A. Yes, sir.
Q. And then you applied them --
MR. FULLER: Form.
BY MR. JONES:
Q. -- to particular defendants, correct?
A. I'm sorry. Ask that question again.
Q. Sure.
In looking at pages 41, 42, 43, 44, 45 --
A. Yes, sir.
Q. -- and part of 46, there's charts here laid out under these five methodologies.
A. Yes, sir.
Q. And these are your

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methodologies?
A. Yes, sir.
Q. You came up with these?
A. Yes, sir. Well, came up based on the suspicious order systems in place by these registrants, but, yes, sir.
Q. Okay. And then you incorporated these into your report?
A. Yes, sir.
Q. And then you applied them to particular defendants, correct?
A. I requested they be applied to particular defendants, yes, sir.
Q. Okay. So you -- you selected which defendants are named in each of these tables then?
MR. FULLER: Object to form.
A. Yes.
BY MR. JONES:
Q. Okay. And in none of those tables is Henry Schein mentioned, right?
A. That's correct.
Q. In fact, in each of these methodologies, it's broken out by Cuyahoga County and Summit County, correct?

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A. Yes, sir.
Q. And Henry Schein isn't even named to the Cuyahoga County lawsuit as far as you know, right?
A. That's correct.
Q. And you've been involved in this case, at least as a consultant or otherwise, since 2017?
A. Yes, sir.
Q. Did you ever ask, well, why isn't Henry Schein named to both lawsuits?
A. I did not, sir.
Q. Did anybody come to you and say, hey, do you think we ought to sue Henry Schein in both lawsuits?
A. No, sir.
Q. And when the opportunity came to amend the lawsuit, did you speak up and say, hey, we ought to add Henry Schein to that lawsuit?
A. No.
MR. FULLER: Form.
A. My capacity, I don't make those kind of decisions or statements.
BY MR. JONES:

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Q. Okay. But you're the -- you're the guy, you're the expert on what's an effective SOM system and what's not an effective SOM system for the plaintiffs, right?
A. I am.
Q. And there's not another individual who's been designated as an expert by the plaintiffs to help you in analyzing whether or not a SOM system is compliant or noncompliant?
A. That is a correct statement, yes, sir.
Q. Okay. And sitting here today, you don't know the number of suspicious orders that Henry Schein has distributed into Summit County?
A. If you're asking do I have a specific number of orders, I do not.
Q. Okay. In fact, you don't know if any suspicious orders have been distributed by Henry Schein into Summit County, do you?
A. I don't state that in my report, no, sir.

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Q. Okay. And similarly, you don't know what, if any, orders that Henry Schein distributed into Summit County were diverted?
(Document review.)
A. I do not have knowledge of any drugs that were diverted.
BY MR. JONES:
Q. As part of your work in this case, you reviewed Henry Schein's standard operating procedures?
A. Yes, sir.
Q. Or SOPs?
A. Yes, sir.
Q. You also reviewed Henry Schein witness deposition testimony?
A. I'm just checking. I don't have a recollection of that.
(Document review.)
A. Yes, sir, I believe I did.
BY MR. JONES:
Q. Do you recall whose?
A. Abreu.
Q. Is that a man or a woman, do you know?
A. I don't recall. I remember the

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name.
Q. Okay. And do you know what Abreu's position was within Henry Schein?
A. I don't recall.
Q. Do you remember -- do you remember anything from reading that witness' deposition?
A. I remember the name and looking at some of the -- you know, re-reviewing some of the cites here in the deposition.
Q. Okay.
A. But I don't have any direct recollection without getting out the deposition and reviewing it.
Q. All right. If you would, would you flip over to page 137 of your report, and if you look down, the last full paragraph starting with Orders.
Do you see that?
A. Yes, sir.
Q. And there -- and you wrote this, correct?
A. Yes, sir.
Q. And there you wrote: Orders that are, quote, identified as suspicious

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will pend for review, closed quote.
A. Yes.
Q. And do you have an understanding as to what "pend" means?
A. Yes, be held or stop.
Q. Okay. Is that like being blocked?
A. Yes, sir, that could be another term.
Q. Okay. Which is something that you talked about earlier when being questioned by McKesson's lawyer?
A. I think I've discussed it all day long, but yes, also with McKesson.
Q. I think you have.
And if an order is blocked or pend or held, it's not being diverted, is it?
A. That's correct.
Q. And there you cite -- it's footnote 642.
Do you see that?
A. Yes, sir.
Q. Do you know what you're referencing there?
A. I have to get the document.

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Q. Well, I will tell you that you're referencing a standard operating procedure for Henry Schein. Do you remember the date?
A. No, I'd like to get the document.
Q. Sure. If you'd like to take a look at it, that's fine.
(Document review.)
A. 404228 or 4226, I'm sorry?
BY MR. JONES:
Q. 4228.
A. I have 4226. I do not have that document. I'll take a look one more time.
Q. I'll tell you what. I'll just tear mine out and we'll use it as an exhibit, if you don't mind.
(Whereupon, Deposition Exhibit Rafalski-17, Henry Schein SOP, HSI-MDL-00404226 - HSI-MDL-00404228, was marked for identification.)
BY MR. JONES:
Q. All right. I'm going to mark as Exhibit 17 kind of a ratty copy --

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A. That's okay.
Q. -- of the document that we've been talking about. Why don't you take a look at that, and just so the record is clear, we're looking at page 137 of your report in connection with the statement that you write: Orders that are, quote, identified as suspicious will pend for review, closed quote.
And footnote 642, which references what I've marked as Exhibit 17. Does that comport with your understanding?
A. Yes, sir.
Q. And can you tell us what that is?
A. What this is?
Q. Yeah.
A. The title is Henry Schein Inc. Verifications, and it says Procedures For Controlled Drug Orders. The date is February 5th, 1998, document number RB-Verification.
Q. Okay.
A. Approved by and there's a signature.

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Q. Okay. But that's a 1998 standard operating procedure, correct?
A. Yes, sir.
Q. And that's what you refer to as part of Henry Schein's practice of pending orders that are deemed -- that are identified as suspicious, correct?
A. Yes, sir.
Q. Okay. And your understanding in looking through Henry Schein's policies and procedures and reviewing the deposition testimony is that Henry Schein would also provide monthly reports to DEA that identified all of the orders pended.
Do you remember that?
A. Yes, sir.
Q. And you're critical of that because that's not done as promptly as you think it should?
A. That would be one of my criticisms, that those orders are provided at a time that's after the shipment.
Q. No, let's back up a little bit.
We just got through talking about how if an order is pended, it doesn't

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ship, right?
A. Yes, sir, maybe I misunderstood the question. I'm sorry.
Q. I think you did. I think you did.
When Henry Schein sends their pended order reports to the DEA on a monthly basis, those orders are pended, correct?
A. Held orders?
Q. Yes.
A. Yes, sir.
Q. So they're not being shipped, are they, pending review?
A. That would be a correct assumption of this -- that statement, yes, sir.
Q. Okay. And do you know how long Henry Schein provided the monthly pended reports to DEA?
(Document review.)
BY MR. JONES:
Q. If you don't mind, let me help you out just to kind of move things along.
A. Sure.
Q. If I represented to you that

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Henry Schein provided monthly pended reports to DEA from the mid to late 1990s up until April 2015, sitting here today, do you have any reason to disagree with that?
A. I would have no reason to accept it or disagree with it, sir.
Q. Okay. And they stopped in April of 2015. Do you know why?
A. No, sir.
Q. Would it surprise you to know that the reason why they stopped is because the DEA told them to stop sending them the pended reports?
A. That would not -- if your question is would that surprise me --
Q. Right.
A. -- it would not because if it was a communication to the DEA that was not a suspicious order and it was a held order, I would -- I would believe that the DEA would want a report of suspicious orders.
Q. Okay. Do you know whether or not as part of the pended order reports that were delivered monthly also included a list of those orders deemed suspicious following

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Henry Schein's investigation?
A. Let me see if I state that in my report. I don't have independent recollection of that.
Q. So you don't know one way or the other?
A. No, I'm not saying that.
Q. Okay.
A. I'm just saying I don't have a direct recollection when you state it that way.
Q. How is that different than what I asked? Let me back up then.
Sitting here today, do you know one way or the other whether or not Henry Schein provided monthly suspicious order reports along with the pended order reports?
A. The statement I make in my report is for the time period of 2009 to 2018, that there were no suspicious orders reported in the CT1 jurisdiction.
Q. Well, I know -- I --
A. I --
Q. Mr. Rafalski, I get that.
A. Okay.

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Q. I mean, but that's specific to Summit County, isn't it?
A. Yes, sir.
Q. That doesn't pertain to Henry Schein and how they do business elsewhere, does it?
A. It does not.
Q. And you're familiar with Craig McCann's characterization of Henry Schein's business in Summit County, are you not?
A. No, I'm not sure what statement you're making there.
Q. Okay. Are you familiar with -- do you know that he gave a deposition last week?
A. I -- he did give a deposition.
Q. And you probably haven't had a chance to review the testimony yet, have you?
A. I have not.
Q. Have you had a chance to talk to him about it?
A. No, sir.
Q. Would it surprise you to know that he characterized Henry Schein's dealings with Summit County as de minimis?

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A. I would have no reason not to believe your statement that that's what he said.
Q. Do you know if DEA has ever expressed any criticisms about Henry Schein's suspicious order monitoring system?
A. I'm not aware of any communication from the DEA to Henry Schein in regards to that topic.
Q. Mr. Rafalski, can reasonable minds disagree as to whether or not an order is suspicious?
A. I think there's always the potential for a disagreement of -- if you're talking about designing a system and what's suspicious. I think it's the subsequent due diligence that confirms or not the accuracy of whether or not an order is suspicious.
So just the nature of an agreement or disagreement on what defines a suspicious order, you mean the definition of it or what it is, I guess?
Q. Can reasonable minds disagree as to whether or not a particular order is suspicious?

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A. I think, yes, I would answer yes to that question.
MR. JONES: All right. No further questions. I'll pass the witness. Thank you.
THE VIDEOGRAPHER: Going off the record at 6:16 p.m.
(Proceedings recessed at 6:16 p.m.)
--o0o--

CERTIFICATE

I, MICHAEL E. MILLER, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that prior to the commencement of the examination, JAMES E. RAFALSKI was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that pursuant to FRCP Rule 30, signature of the witness was not requested by the witness or other party before the conclusion of the deposition.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

MICHAEL E. MILLER, FAPR, RDR, CRR
Fellow of the Academy of Professional Reporters
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Notary Public
My Commission Expires: 7/9/2020
Dated: May 15, 2019

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After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

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ACKNOWLEDGMENT OF DEPONENT

I, JAMES E. RAFALSKI, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
JAMES E. RAFALSKI DATE

Subscribed and sworn to before me this
_____ day of _____, 20 _____.
My commission expires: _____

_____
Notary Public

LAWYER'S NOTES

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